# EXHIBIT I

Page 1

# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., MDL NO.: 2326

PELVIC REPAIR SYSTEM

PRODUCTS LIABILITY LITIGATION

#### THIS DOCUMENT RELATES TO:

Chapa v. Boston Scientific Corporation 2:13-cv-17511

Fisher v. Boston Scientific Corporation 2:13-cv-29324

Flandro v. Boston Scientific Corporation 2:13-cv-17027

Toronto, Ontario, Canada
Wednesday, December 17, 2014
VOLUME I

Videotaped Deposition of VLADIMIR IAKOVLEV,
M.D., a witness herein, called for examination

by counsel for the Defendants in the above-mentioned

matter, the witness having been affirmed, taken at the

offices of Neesons Reporting, 141 Adelaide Street West,

Toronto, Ontario, at 9:11 a.m., on Wednesday, December 17,

2014, and the proceedings being taken down by Stenotype

and transcribed by JUDITH M. CAPUTO, RPR, CSR, CRR.

	Page 2		Page 4
1 2	THIS DOCUMENT RELATES TO: (Cont'd)	1 2	APPEARANCES: (Cont'd)
3	Fleming v. Boston Scientific Corporation 2:12-cv-05131	3	ON BEHALF OF THE PLAINTIFFS:
4	Franco v. Boston Scientific Corporation 2:12-cv-07248	4	BY: CRAIG EILAND, ESQ.
5	Hanson v. Boston Scientific Corporation 2:13-cv-10653	5	, ,
6	Hoffman v. Boston Scientific Corporation 2:12-cv-04433		Law Offices of Craig Eiland 2211 The Strand, Suite 201
7	Howard v. Boston Scientific Corporation 2:12-cv-04145	7	
8	Kilgore v. Boston Scientific Corporation 2:12-cv-04145	8	Galveston, Texas 77550
9	Parker v. Boston Scientific Corporation 2:12-cv-01243	9	409.763.3260
	Reynolds v. Boston Scientific Corporation 2:12-cv-01245		
10			ON BEHALF OF THE DEFENDANTS:
11	Robbins v. Boston Scientific Corporation 2:12-cv-01413	11	BY: ADRIENNE L. BYARD, ESQ.
12	Tame v. Boston Scientific Corporation 2:13-cv-01059	12	Shook, Hardy & Bacon, LLP
13	Watanabe v. Boston Scientific Corporation 2:13-cv-12227		2555 Grand Boulevard
14		14	Kansas City, Missouri 64108
15		15	816.474.6550
16	APPEARANCES:	16	
17		17	ALSO PRESENT:
18	ON BEHALF OF THE PLAINTIFFS:	18	DENNIS COSTIGAN, Motley Rice LLC
19	BY: JONATHAN D. ORENT, ESQ.	19	
20	Motley Rice, LLC	20	
21	321 South Main Street, 2nd Floor	21	
22	Providence, Rhode Island 02903	22	
23	401.457.7723	23	
24		24	
25		25	
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1	APPEARANCES:	1	INDEX
2		2	
3	ON BEHALF OF THE PLAINTIFFS:	3	WITNESS: VLADIMIR IAKOVLEV, M.D.
4	BY: ALAN S. LAZAR, ESQ.	4	PAGE
5	Marlin Saltzman, LLP	5	DIRECT EXAMINATION BY MS. BYARD8
6	29229 Canwood Street, Suite 208	6	
7	Agoura Hills, California 91301	7	
8	818.991.8080	8	
9	010.991.0000	9	
10	ON BEHALF OF THE PLAINTIFFS:	10	
11	BY: NATHAN C. BESS, ESQ.	11	INDEX OF EXHIBITS
12	Aylstock, Witkin, Kreis & Overholtz	12	
13	17 East Main Street, Suite 200	13	NUMBER/DESCRIPTION PAGE NO.
14	Pensacola, Florida 32502	14	1195: Notice of Videotaped Deposition 10
15	850.202.1010	15	Duces Tecum of Dr. Vladimir Iakovlev.
16	050.202.1010	16	1196: General Expert Report of 27
17	ON BEHALF OF THE PLAINTIFFS:	17	Dr. Iakovlev dated November 10, 2014.
18	BY: KATY KROTTINGER, ESQ.	18	1197: Article entitled, "Mesh-Related 80
19	The Monsour Law Firm	19	SIN Syndrome: A Surreptitious Irreversible
20	404 North Green Street	20	Neuralgia and Its Morphologic Background
		21	in the Etiology of Post-Herniorrhaphy Pain,"
21	Longview, Texas 75606	22	In the Ethology of Tost-Hermormaphy Fam,  International Journal of Clinical
22	903.758.5757	23	Medicine, 2014, by Dr. R. Bendavid,
23		24	Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev.
24 25		25	Di. W. Lou, Di. A. Kocii aliu Di. V. Idkovicv.

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1	1198: International Scholarly and 156	1	Defendant, Boston Scientific.
2	Scientific Research & Innovation, 2014,	2	MR. EILAND: Craig Eiland for the
3	Publication entitled, "Pathology of	3	Plaintiffs.
4	Explanted Transvaginal Meshes," by	4	THE VIDEOGRAPHER: Thank you.
5	Dr. V. Iakovlev, Dr. E. T. Carey and	5	The court reporter is Judy Caputo, CSR,
6	Dr. J. Steege.	6	and who will now swear in or affirm the witness.
7	1199: Abstract entitled, "Pathological 186	7	Whereupon,
8	Findings of Transvaginal Polypropylene	8	VLADIMIR IAKOVLEV, M.D.,
9	Slings Explanted for Late Complications:	9	called for examination by counsel for Defendants
10	Mesh is Not Inert," by Dr. V. Iakovlev,	10	and having been affirmed by me, was examined and
11	Dr. G. Mekel and Dr. J. Blaivas.	11	testified as follows:
12	1201: Abstract entitled, "In-vivo 207	12	DIRECT EXAMINATION BY MS. BYARD:
13	Degradation of Surgical Polypropylene	13	Q. Dr. Iakovlev, it's very nice to
14	Meshes: A Finding Overlooked for	14	see you again. You'll recall I'm Adrienne Byard.
15	Decades," by Dr. V. Iakovlev,	15	I think the last time we had the opportunity to
16	Dr. S. Guelcher, Dr. R. Bendavid.	16	talk was in January of 2014, when I took your
17	Dr. S. Guerener, Dr. R. Bendavid.	17	deposition here in Toronto. Do you remember that
18		18	deposition?
19		19	A. Yes, I do.
20		20	Q. And since that time you've been
21		21	deposed again; correct?
22		22	A. By Boston Scientific, yes.
23		23	Q. And also by other mesh
24		24	manufacturers, right?
25		25	A. Yes, that's correct.
	Page 7		Page 9
1	Upon commencing at 9:11 a.m.	1	Q. Okay. And you've also had the
2	Opon commencing at 7.11 a.m.	2	opportunity to testify at some trials; correct?
3	THE VIDEOGRAPHER: Good morning. We	3	A. Yes.
4	are now on the record. My name is Peter Goodale,	4	
5	· · · · · · · · · · · · · · · · · · ·		
_	certified legal videographer for Golkow Technologies		Q. Let's work forwards in time.
6	certified legal videographer for Golkow Technologies.  Today's date is December 17, 2014, and	5	So from January 2014, when I took your
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7 8 9 10 11 12	Today's date is December 17, 2014, and the time on the video monitor is 9:11 a.m.  This video deposition is being held in Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326.	5 6 7 8 9 10 11	So from January 2014, when I took your deposition here in Toronto, when was your next deposition?  A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March  Q. Let me stop you there, if you don't mind. Were those in an AMS matter?  A. Yes.
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3 (Pages 6 to 9)

A Then there was one for Ethicon in April.  Q. Okay. A. But that's not a memory test. The recent depositions is provided on the flash drive for you.  Q. Okay. So you've brought some materials with you here today through counsel in response to our request. Is that what you're saying?  A. That's correct. Q. Okay. And we'll go ahead and mark as 1195, the Notice of Deposition. I'll pass a copy of that to you.  EXHIBIT NO. 1195: Notice of Videotaped Deposition Duces Tecum of Dr. Vladimir I Akovlev.  BY MS. BYARD: Q. Is this deposition notice, or one similar to it, familiar to you, sir? A. Yes. Q. What were the documents, as far as  I Q. You said "my obligations"? A. No, no, I didn't say that. Q. Oh, really? Okay, I missed it then. Somewhere between "medical records for Plaintiffs" and the "billing for Plaintiffs"  MR. ORENT: He said "publications. BY MS. BYARD: Q. "Publications." Publications, thank you so much. In deposition, I'm sure, that if there are times where deposition and I'll ask that you do the same all right? A. Sure. Q. If you don't ask for clarification, I'll assume you understood me, A. (Witness nods). Q. Is that fair? A. Yes. Q. Very good. What else was, besides your publications, the medical records for Plaintiffs, is on that thumb drive, so far as you know?	nen
2 April. 3 Q. Okay. 4 A. But that's not a memory test. The 5 recent depositions is provided on the flash drive 6 for you. 7 Q. Okay. So you've brought some 8 materials with you here today through counsel in 9 response to our request. Is that what you're 10 saying? 11 A. That's correct. 12 Q. Okay. And we'll go ahead and mark 13 as 1195, the Notice of Deposition. I'll pass a 14 copy of that to you. 15 EXHIBIT NO. 1195: Notice of Videotaped 16 Deposition Duces Tecum of Dr. Vladimir 17 Iakovlev. 18 BY MS. BYARD: 19 Q. Is this deposition notice, or one 20 similar to it, familiar to you, sir? 21 A. Yes. 22 Q. And did you bring documents 23 responsive to our request through counsel? 24 A. No, no, I didn't say that. 3 Q. Oh, really? Okay, I missed it 4 then. Somewhere between "medical records for Plaintiffs" and the "billing for Plaintiffs" 4 then. Somewhere between "medical records for Plaintiffs" and the "billing for Plaintiffs" 6 MR. ORENT: He said "publications. BY MS. BYARD: 9 (Publications. Publications, we don't understand each other, I'll ask for clarification and I'll ask that you do the same all right? 15 A. Sure. 16 Q. If you don't ask for clarification, I'll assume you understood me, 17 Clarification, I'll assume you understood me, 18 A. Yes. 20 A. Yes, that's fair. 21 Q. Very good. 22 What else was, besides your responsive to our request through counsel? 23 publications, the medical records you review Plaintiffs, and the billings for Plaintiffs, is on	nen
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6 for you. 7 Q. Okay. So you've brought some 8 materials with you here today through counsel in 9 response to our request. Is that what you're 10 saying? 11 A. That's correct. 12 Q. Okay. And we'll go ahead and mark 13 as 1195, the Notice of Deposition. I'll pass a 14 copy of that to you. 15 EXHIBIT NO. 1195: Notice of Videotaped 16 Deposition Duces Tecum of Dr. Vladimir 17 Iakovlev. 18 BY MS. BYARD: 19 Q. Is this deposition notice, or one 19 Similar to it, familiar to you, sir? 20 Similar to it, familiar to you, sir? 21 A. Yes. 22 Q. And did you bring documents 23 responsive to our request through counsel? 24 A. Yes.  6 MR. ORENT: He said "publications.  8 BY MS. BYARD:  9 thank you so much.  10 You'll remember the rules of the deposition, I'm sure, that if there are times where are tim	nen
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19 Q. Is this deposition notice, or one 20 similar to it, familiar to you, sir? 21 A. Yes. 22 Q. And did you bring documents 23 responsive to our request through counsel? 24 A. Yes. 29 Q. Is that fair? 20 A. Yes, that's fair. 21 Q. Very good. 22 What else was, besides your 23 publications, the medical records you review 24 Plaintiffs, and the billings for Plaintiffs, is on	, , , , , , , , , , , , , , , , , , ,
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responsive to our request through counsel?  23 publications, the medical records you review A. Yes.  24 Plaintiffs, and the billings for Plaintiffs, is on	
24 A. Yes. 24 Plaintiffs, and the billings for Plaintiffs, is on	ed for
2. What were the documents, as far as 12 and as 14 as 15 and as 15	
Page 11 Page 11	.ge 13
1 you understand it, that were being brought here 1 A. The list of testimonies I gave.	.50 10
2 today in response to our request? 2 Q. Okay.	
3 A. Medical records I reviewed for the 3 A. My current CV.	
4 Plaintiffs. My publications, billing I produced 4 Q. You don't have a paper copy of	f
5 for the Plaintiffs, which were identified in this 5 that that I could review and go over with y	
6 notice. 6 of any of those materials?	ou now
7 Q. Okay. 7 A. No, I didn't bring them. I tried	ı
8 A. For whatever reason, there is no 8 to save trees.	ı
9 list here. It looks different than what I  9 Q. Okay. Well, we'll take that up	on
10 received. 10 a break.	311
11 Q. Right. The list you saw, and I'll 11 I want to return to this list of	
just show you this we're not going to mark it at 12 depositions. So you gave a deposition in	April or
13 this point but it was a longer list like this,  13 in that timeframe for Ethicon, have you gi	
14 right? 14 depositions in any cases involving any other.	
15 A. Yes. That looks more familiar 15 manufacturers of transvaginal mesh?	
16 than this. 16 A. Yes.	
17 Q. Okay. And so you brought the 17 Q. Okay. Which others?	
18 billing that pertained to those women's cases, 18 A. Bard.	
19 right? 19 Q. When was that deposition?	
20 A. Um-hum. 20 A. Let me turn it up. The deposit	ion
21 Q. Okay. 21 for Bard was in November.	
22 A. Yes. 22 Q. November. Now you've also	
Q. Now, when you say "obligations," 23 testified at some trials; correct?	
24 what do you mean by that? 24 A. That's correct.	
25 A. What do you mean? 25 Q. What trials have you testified	

4 (Pages 10 to 13)

Page 14 Page 16 1 and when were they? 1 tissue and mesh samples, observed any differences 2 A. Both were for Boston Scientific 2 that you believe would increase or decrease the 3 3 devices. One trial was in August for Ms. Cardenas risk of clinical complications in women, depending and the other one was in Miami for Ms. Eghanayem 4 on the type of mesh that is used? 4 5 5 and other patients. MR. ORENT: Objection. 6 Q. Going back to depositions, you 6 THE WITNESS: Define "type." Different 7 7 also had -- besides the time that I took your manufacturer, different device, different knit 8 deposition in January with Ms. Weiler for Boston 8 pattern? I mean, what, what exactly --9 BY MS. BYARD: 9 Scientific, you also had a deposition in July, 10 10 where you covered, specifically, the Cardenas and Q. Any of those are fine. It's an 11 the Eghanayem matters, right? 11 open-ended question. 12 12 A. That's correct. A. In some lightweighter meshes, 13 Q. So all told, you've been deposed 13 there is more inclusion of normal tissue into the 14 once in the Boston Scientific MDL; once for two 14 pores. The difference is not drastic, but there 15 specific cases in the Boston Scientific MDL; once 15 is -- at the same time, these lightweight meshes 16 for Ethicon --16 fold easier, so it defeats the purpose of the 17 A. Twice. 17 design. 18 O. Twice for Ethicon. Then a 18 But theoretically, they're flat. They 19 would behave better than those more heavier with 19 deposition for Bard? 20 A. Twice for Bard. 20 less pores. I mean, there are drawbacks and cons 21 Q. Twice for Bard. And so we're in 21 and pros of this, but the design behaves slightly 22 22 differently than other designs -- than heavier the neighborhood of six or seven depositions? 23 23 A. That's correct. weight designs. That's what I can say. 24 O. And two trials? 24 Q. So at this point, based on your 25 A. That's correct. 25 observations to date, you're not in a position to Page 15 Page 17 1 say that those designs are safer or would minimize 1 Q. Because we've already covered so 2 many of your opinions with you in these other 2 the risk of clinical complications in women, right? 3 depositions and at trials, I'm not going to rehash 3 MR. ORENT: Objection. THE WITNESS: Not to a noticeable degree. 4 a bunch of old ground with you. 4 5 5 I'd like to specifically cover with you BY MS. BYARD: 6 today, your deposition for these wave cases, this 6 Q. Okay. 7 general report that you've authored. It's roughly 7 A. To detectable degree. 8 I see they behave differently, the 8 the 93-page report that was submitted in the wave 9 tissue reacts differently. But all of them came to 9 cases, all right? 10 10 me because of complications. And then I'd also like to cover with 11 Q. Right. 11 you some of the updates to your opinions, if any, 12 12 A. So I ended up with specimens which okay, sir? 13 13 A. (Witness nods.) are excised complications. Therefore, 14 Q. Has your opinion across these 14 complications occurred in those. 15 depositions and trials been basically the same? 15 Q. And I believe you noted in one of 16 And by that I mean, that the tissue response that 16 your original reports, that there's mesh that has 17 you see the polypropylene mesh is essentially 17 tangs and mesh that doesn't have tangs, comparing Boston Scientific mesh either between products or 18 similar across all the various manufacturers? 18 19 19 MR. ORENT: Objection. Boston Scientific mesh to other products; do you THE WITNESS: Yes, to a degree. I 20 20 recall that distinction? 21 learn a little bit more after examining more 21 A. Yes, there is distinction. I 22 22 specimens, more details. But basic principles mean, some are tanged; heat treated them in slings, 23 remain the same. 23 but they're not treated along all lengths. Some 24 24 BY MS. BYARD: are shorter segment. 25 Q. Have you in your observations of 25 So it also behaves somewhat differently.

5 (Pages 14 to 17)

Page 18 Page 20 1 But the end result was they became excised, they 1 after excision, or during in vivo? 2 were problematic. 2 Q. Sure. So you're talking about the 3 3 Q. So similarly, you're not in a shape after excision; correct? position today, based on your observations to date, 4 A. That's correct. 4 5 to testify that the tissue response to the 5 Q. Okay. And when you look at the de-tanged mesh versus tanged mesh, is better or 6 shape after excision, you're not able to say with 6 7 worse in terms of its likelihood of causing 7 certainty, what the shape of the mesh was in vivo, 8 8 complications in women, right? typically, unless it's completely encased in scar 9 9 MR. ORENT: Objection. tissue, right? 10 10 THE WITNESS: That is difficult MR. ORENT: Objection. 11 question. I mean, you're asking likelihood. This 11 THE WITNESS: That's not correct 12 would be more of a clinical question, and to be a 12 statement. I can find features which will give me 13 clinical trial, larger trial. 13 indication what was shape in vivo. I am able to 14 14 I can tell you that there is a say what was shape in vivo. 15 15 BY MS. BYARD: different tissue reaction. And I can tell you that 16 my specimens came to me because patients 16 Q. Let's take that up in a little 17 experienced complications. 17 bit, if you don't mind. 18 But I would not be able to give you a 18 Returning, though, to your statement 19 19 that the heat-treated edges don't curl, was that statement of what's the percentage of improvement 20 or, or lack of improvement. 20 your basic observation? 21 BY MS. BYARD: 21 A. Generally, yes. 22 22 Q. And you wouldn't be able to say O. Okay. And so the de-tanged 23 that to a reasonable degree of certainty, right? 23 sub-urethral portion of the Boston Scientific mesh 24 MR. ORENT: Objection. 24 slings had a lesser propensity to curl? 25 THE WITNESS: I just wouldn't be able 25 A. That's correct. Page 19 Page 21 1 MR. ORENT: Objection. 1 to say that. And these factors, the efficacy, it 2 was a clinical question that had to be a long-term 2 BY MS. BYARD: 3 clinical study. 3 Q. In terms of the tissue response, 4 BY MS. BYARD: 4 the amount of inflammation that you've seen was the 5 5 same between de-tanged and non-de-tanged mesh, O. Okay. What were the -- you said 6 there are some differences. What were the tissue 6 though? 7 responses that you've seen that are different 7 A. It's exactly the same. There is 8 8 between tanged and de-tanged mesh? no difference. No detectable difference. A. If it's tanged, the edges don't 9 Q. And you make a distinction between 9 10 curl as much. So if it's a sling, I can see 10 an inflammatory response that you see under a clearer difference. When it gets excised, the 11 microscope and a foreign body reaction; correct? 11 12 heat-treated portion doesn't curl. But then there 12 A. A foreign body reaction is an 13 13 is a sharp transition into non-heat-treated inflammatory response. I don't make a distinction. 14 portions, and they curl. 14 Q. Okay. 15 So if those slings were not -- I mean, 15 A. I make distinction between types 16 original slings were not heat-treated, so the whole 16 of inflammatory reaction. length is curled into a rope. But if there is 17 17 Q. In particular, whether or not 18 there is a presence of multinucleated cells or 18 section is treated, that section doesn't curl, but 19 19 the ends curl. So I can see the difference. But giant cells? 20 20 the design failed in one way or another. A. These are just microfibers who 21 21 Q. And so a distinction I might try decided to become multinucleated. So there is no 22 and make throughout the day, and I want to make 22 difference between multinucleated microphage and 23 sure it's accurate. You're talking about the shape 23 single nucleated microphage. Functionally, 24 of the mesh itself, right, if it curls --24 genetically, they're all the same. 25 A. Shape before insertion, or shape 25 Q. Does it tell you whether or not

6 (Pages 18 to 21)

	Page 22		Page 24
1	the inflammatory reaction is in response to a	1	complete the billing.
2	foreign body, though, depending on the type of	2	BY MS. BYARD:
3	macrophage?	3	Q. But you will by the time you file
4	A. No. All macrophage is a reaction	4	your taxes?
5	to foreign body.	5	A. Yes.
6	Q. Okay.	6	Q. And when do you anticipate doing
7	A. If there is a foreign body, and	7	that?
8	there are macrophages, they're reacting. Because,	8	A. Next spring.
9	generally, the foreign body or granulomatous	9	Q. Did you do anything to prepare for
10	reaction is defined as epithelioid histiocytes or	10	your deposition today?
11	macrophages.	11	A. I prepared documents for you on
12	Q. So if my question were whether you	12	the flash drive.
13	had seen any difference in the foreign body	13	Q. Did you meet with counsel to
14	reaction between de-tanged and tanged meshes, your	14	review documents?
15	answer would be the same; wouldn't it? No, you	15	A. Yes, we met yesterday.
16	didn't see a difference?	16	Q. Have you prepared by phone for
17	MR. ORENT: Objection. Asked and	17	your deposition here today?
18	answered.	18	A. No.
19	THE WITNESS: That's correct. I did	19	Q. How long did you meet yesterday?
20	not see the difference.	20	A. A couple of hours.
21	BY MS. BYARD:	21	Q. And did you review any materials
22	Q. Okay. I want to look at your	22	that weren't provided on that flash drive?
23	billing records once we have copies of them, but do	23	A. No, we just went through whatever
24	you have a number in mind of all told how much	24	was on the flash drive and my reports.
25	you've been paid by Plaintiffs in the mesh	25	Q. Do you intend to bill for the time
	Page 23		Page 25
1	litigation for your expert work against Boston	1	that you spent yesterday with counsel?
2	Scientific?	2	A. Yes.
3	A. It's hard to say now, because I	3	Q. How much is your rate now?
4	don't keep that exact records, really, I'm so busy.	4	A. 475.
5	Last year my income tax return was	5	Q. It's gone up.
6	\$24,000 from depositions and statements. This year	6	
7			A. I published, so I don't think it's
	it's larger. I don't know how much larger.	7	A. I published, so I don't think it's too high. I mean, I see some reports which are
8	Q. Is it two times larger?	7 8	÷
8 9		l .	too high. I mean, I see some reports which are
	Q. Is it two times larger?	8	too high. I mean, I see some reports which are much higher.
9	<ul><li>Q. Is it two times larger?</li><li>MR. ORENT: Objection.</li></ul>	8 9	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh
9 10 11 12	<ul><li>Q. Is it two times larger?</li><li>MR. ORENT: Objection.</li><li>THE WITNESS: Possibly.</li><li>BY MS. BYARD:</li><li>Q. Could it be three times larger?</li></ul>	8 9 10 11 12	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012.
9 10 11	<ul><li>Q. Is it two times larger?</li><li>MR. ORENT: Objection.</li><li>THE WITNESS: Possibly.</li><li>BY MS. BYARD:</li><li>Q. Could it be three times larger?</li><li>MR. ORENT: Objection.</li></ul>	8 9 10 11 12 13	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012?
9 10 11 12 13 14	<ul> <li>Q. Is it two times larger?</li> <li>MR. ORENT: Objection.</li> <li>THE WITNESS: Possibly.</li> <li>BY MS. BYARD:</li> <li>Q. Could it be three times larger?</li> <li>MR. ORENT: Objection.</li> <li>THE WITNESS: I don't want to guess.</li> </ul>	8 9 10 11 12 13 14	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it
9 10 11 12 13 14 15	Q. Is it two times larger? MR. ORENT: Objection. THE WITNESS: Possibly. BY MS. BYARD: Q. Could it be three times larger? MR. ORENT: Objection. THE WITNESS: I don't want to guess. BY MS. BYARD:	8 9 10 11 12 13 14 15	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it became involved in this was end of 2012.
9 10 11 12 13 14 15	<ul> <li>Q. Is it two times larger?</li> <li>MR. ORENT: Objection.</li> <li>THE WITNESS: Possibly.</li> <li>BY MS. BYARD:</li> <li>Q. Could it be three times larger?</li> <li>MR. ORENT: Objection.</li> <li>THE WITNESS: I don't want to guess.</li> <li>BY MS. BYARD:</li> <li>Q. What would you need to do to</li> </ul>	8 9 10 11 12 13 14 15	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it became involved in this was end of 2012. Q. And that was your work with
9 10 11 12 13 14 15 16	Q. Is it two times larger? MR. ORENT: Objection. THE WITNESS: Possibly. BY MS. BYARD: Q. Could it be three times larger? MR. ORENT: Objection. THE WITNESS: I don't want to guess. BY MS. BYARD: Q. What would you need to do to calculate for me how much money you've been paid by	8 9 10 11 12 13 14 15 16	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it became involved in this was end of 2012. Q. And that was your work with Dr. Bendavid on hernia meshes; correct?
9 10 11 12 13 14 15 16 17	Q. Is it two times larger? MR. ORENT: Objection. THE WITNESS: Possibly. BY MS. BYARD: Q. Could it be three times larger? MR. ORENT: Objection. THE WITNESS: I don't want to guess. BY MS. BYARD: Q. What would you need to do to calculate for me how much money you've been paid by plaintiffs for acting as an expert against mesh	8 9 10 11 12 13 14 15 16 17	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it became involved in this was end of 2012. Q. And that was your work with Dr. Bendavid on hernia meshes; correct? A. That's correct.
9 10 11 12 13 14 15 16 17 18	Q. Is it two times larger? MR. ORENT: Objection. THE WITNESS: Possibly. BY MS. BYARD: Q. Could it be three times larger? MR. ORENT: Objection. THE WITNESS: I don't want to guess. BY MS. BYARD: Q. What would you need to do to calculate for me how much money you've been paid by plaintiffs for acting as an expert against mesh manufacturers?	8 9 10 11 12 13 14 15 16 17 18	too high. I mean, I see some reports which are much higher.  Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?  A. 2012. Q. 2012? A. Yeah, first time I saw it became involved in this was end of 2012. Q. And that was your work with Dr. Bendavid on hernia meshes; correct?  A. That's correct. Q. And then in 2013 you were
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7 (Pages 22 to 25)

	Page 26		Page 28
1	was my first transvaginal specimen. Probably an	1	You recognize it, though?
2	attorney, probably Dr. Thomson asked me to look at	2	A. Yes, this is my document.
3	it. Maybe, maybe not. I don't know, I don't	3	Q. And if you flip into the document,
4	remember now.	4	you'll see your signature on it? Hopefully.
5	BY MS. BYARD:	5	MR. ORENT: Page 65.
6	Q. Okay. And originally your rate	6	THE WITNESS: Yes, I do.
7	was \$400, and now it's \$475, right?	7	BY MS. BYARD:
8	A. That's correct.	8	Q. What date did you sign this report?
9	Q. And why did you increase your	9	A. November 10th.
10	rate?	10	Q. When did you start working on it?
11	A. As I said, I published, I'm more	11	A. This is a general report, so
12	experienced. It wouldn't be unfair, because when I	12	essentially, this has been transformed original
13	started I had no experience in litigation cases.	13	report. We discussed in January, so it just was
14	Q. So since beginning work on	14	modified several times, reformatted and new images
15	transvaginal mesh matters in 2013, and now sitting	15	were inserted so
16	here today at the end of 2014, you've now published	16	If you ask me when I started working on
17	articles on the subjects of this litigation; correct?	17	this, it would be probably two thousand and
18	A. No, this is not correct. I didn't	18	early late 2013.
19	publish on the subject of litigation. I published	19	Q. Okay. Have you issued similar
20	on my research, on topics of surgical polypropylene	20	reports, reports in formatting similar to this one
21	meshes.	21	in the other mesh manufacturers' cases?
22	Q. Based on your review of specimens	22	A. Yes. Usually we keep the same
23	provided to you by Plaintiffs' attorneys in	23	format, general report and case-specific reports.
24	litigation?	24	Q. Visually, this report appears
25	MR. ORENT: Objection.	25	different than the report I originally deposed you
	Page 27		Dama 20
	1436 17		Page 29
1	THE WITNESS: Most publications	1	about in January of 2014. Do you agree with me
1 2		1 2	
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2	THE WITNESS: Most publications actually are based on hernia meshes, which were	2	about in January of 2014. Do you agree with me about that?
2 3	THE WITNESS: Most publications actually are based on hernia meshes, which were coming from just regular patients. I examined more	2	about in January of 2014. Do you agree with me about that?  A. Yes. This is more structured.
2 3 4	THE WITNESS: Most publications actually are based on hernia meshes, which were coming from just regular patients. I examined more specimens for litigation, but publications are	2 3 4	about in January of 2014. Do you agree with me about that?  A. Yes. This is more structured.  Because I understood that, medically, though
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8 (Pages 26 to 29)

	Page 30		Page 32
1	case-specific reports today, but some of them	1	testing in a laboratory environment."
2	revert to the earlier format that you used, right?	2	Did I read that correctly?
3	A. Yes.	3	A. Yes, that's correct.
4	Q. But the exhibit that we're looking	4	Q. I believe we previously
5	at, 1196, this reflects the most I guess your	5	established, but I wanted to make sure in light of
6	most distilled version of your opinions in this	6	this language, that you haven't reviewed any of
7	litigation; is that fair?	7	Boston Scientific's internal testing?
8	A. I don't know about distilled, but	8	A. No, not specifically Boston
9	it's most updated version, most recent.	9	Scientific.
10	Q. So if we wanted to talk about your	10	Q. Okay. And have you reviewed any
11	current opinions, it would be better for us to work	11	of Boston Scientific's biocompatibility testing?
12	off of 1196 than the version that I deposed you	12	A. No, not internally.
13	about in January of 2014, right?	13	Q. Have you reviewed any of Boston
14	A. Yes, it would be easier.	14	Scientific's animal testing?
15	Q. Okay. Notwithstanding the fact	15	A. As I said, I had no access to
16	that that older version appears inserted in some of	16	specifically internal documents of Boston Scientific.
17	these case-specific reports that we'll talk about	17	Q. Would it interest you, as a
18	tomorrow, right?	18	pathologist, to see what Boston Scientific's animal
19	A. That's correct.	19	testing revealed about the tissue response to its
20	Q. Okay, good. Turning to your	20	products?
21	report, we start off with your qualifications. Are	21	A. Yes, it would be interesting.
22	you with me?	22	Q. Is that anything that you
23	A. Yes, I am.	23	requested from the Plaintiffs' counsel?
24	Q. Have there been and then we	24	MR. ORENT: Objection.
25	have attached as an exhibit to your report, we have	25	THE WITNESS: It didn't occur to me
25		23	
	Page 31		Page 33
1	your CV; true?	1	that you would provide it.
2	A. Yes, I saw it.	2	BY MS. BYARD:
3	Q. I think it's Exhibit A.	3	Q. And similarly, you haven't done a
4	Apart from the publications that I'll	4	review of the literature for clinical studies
5	talk about here in a moment as they come up in the	5	conducted on Boston Scientific's products, right?
6	report, have there been any other updates to your	6	MR. ORENT: Objection.
7	CV or your qualifications?	7	THE WITNESS: Repeat
8	A. Publications, presentations,	8	MR. ORENT: Hold on one second.
9	abstracts, posters, that's main things, nothing	9	Do you mean "randomized control"?
10	else.	10	Because the term "study" has a very specific
11	Q. Okay.	11	meaning in science.
12	A. I'm still working in the same place.	12	MS. BYARD: Counsel, please don't coach
13	Q. Same place, same title?	13	the witness with your objections.
14	A. (Witness nods.)	14	MR. ORENT: No. I'm asking you to
15	Q. Very good. And if we go further	15	clarify the question.
			DIVING DIVIND
16	into your report, you have a section it's the	16	BY MS. BYARD:
16 17	into your report, you have a section it's the second paragraph on page 2. It's the first full	17	Q. Clinical studies, studies in
16 17 18	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.	17 18	Q. Clinical studies, studies in humans.
16 17 18 19	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the	17 18 19	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to
16 17 18 19 20	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the research that you started with Dr. Bendavid, you	17 18 19 20	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to you, sir?
16 17 18 19 20 21	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the research that you started with Dr. Bendavid, you mention in the last sentence that:	17 18 19 20 21	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to you, sir?  A. Please repeat the first question.
16 17 18 19 20 21 22	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the research that you started with Dr. Bendavid, you mention in the last sentence that:  "Previous studies in	17 18 19 20 21 22	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to you, sir?  A. Please repeat the first question. Q. Sure. What does clinical what
16 17 18 19 20 21 22 23	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the research that you started with Dr. Bendavid, you mention in the last sentence that:  "Previous studies in manufacturers' testing have been	17 18 19 20 21 22 23	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to you, sir?  A. Please repeat the first question. Q. Sure. What does clinical what does the term
16 17 18 19 20 21 22	into your report, you have a section it's the second paragraph on page 2. It's the first full paragraph.  Here where you're talking about the research that you started with Dr. Bendavid, you mention in the last sentence that:  "Previous studies in	17 18 19 20 21 22	Q. Clinical studies, studies in humans.  What does "clinical studies" mean to you, sir?  A. Please repeat the first question. Q. Sure. What does clinical what

9 (Pages 30 to 33)

	Page 34		Page 36
1	deposition. What is	1	Q. Okay.
2	MR. ORENT: Are you withdrawing the	2	A. I have piles sitting on my desk
3	prior question?	3	now to sort out, maybe Christmastime.
4	MS. BYARD: Yes, I'll withdraw that.	4	Q. Okay. And so when was the last
5	BY MS. BYARD:	5	time you updated this spreadsheet?
6	Q. What does the term "clinical	6	A. Late August, early September,
7	studies" mean to you as opposed to "preclinical	7	somewhere in that time. It was slow time, so I
8	studies"?	8	could, could do that.
9	A. Clinical studies, when it's	9	MR. ORENT: Vladimir, can you just keep
10	experimentational testing is done on patients.	10	your voice up.
11	Q. Okay. Have you reviewed any of	11	THE WITNESS: Sure, yeah. Just remind
12	The state of the s	12	•
	the clinical studies, so testing on humans, of	13	me.
13	Boston Scientific's products?		BY MS. BYARD:
14	MR. ORENT: Objection.	14	Q. I don't know that we have a copy
15	THE WITNESS: I have reviewed published	15	of the spreadsheet, so that's something that I
16	literature from clinical studies, including Boston	16	would request.
17	Scientific. Usually it's a mix, it's not a	17	A. I provided it in July. I don't
18	separate sometimes it's a separate device, but	18	remember if I updated since then, but it could be a
19	mostly it's a mix.	19	small update.
20	BY MS. BYARD:	20	Q. Okay.
21	Q. Okay. So you couldn't say, you	21	A. But you received a copy in July.
22	couldn't sit here today and testify that you've	22	I think in July it was 97 transvaginal cases.
23	reviewed all 25-plus Obtryx studies, for instance;	23	Q. So I don't, though, have a
24	could you?	24	spreadsheet that would reflect this 120 number of
25	MR. ORENT: Objection. Foundation.	25	samples that appears here in your report, right?
	Page 35		Page 37
1	I think the record speaks to the fact	1	A. I'm not sure if it exists. And,
2	there aren't 25 studies in Obtryx.	2	· ·
_	•		yes, I counted those 97. I know the number because
3	MS. BYARD: Counsel, please, make a	3	yes, I counted those 97. I know the number because I could count them quickly, but they are not
4	MS. BYARD: Counsel, please, make a form objection.		I could count them quickly, but they are not
	form objection.	3	I could count them quickly, but they are not entered in the spreadsheet.
4	form objection.  THE WITNESS: I have a large hard drive	3 4	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up
4 5 6	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't	3 4 5 6	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.
4 5 6 7	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so	3 4 5 6 7	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all
4 5 6 7 8	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical	3 4 5 6 7 8	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report
4 5 6 7 8 9	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.	3 4 5 6 7 8 9	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?
4 5 6 7 8 9	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD:	3 4 5 6 7 8 9	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.
4 5 6 7 8 9 10	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next	3 4 5 6 7 8 9 10	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen
4 5 6 7 8 9 10 11	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD:  Q. Okay. I want to turn to the next paragraph here in this preface to your report,	3 4 5 6 7 8 9 10 11	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the
4 5 6 7 8 9 10 11 12 13	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh	3 4 5 6 7 8 9 10 11 12 13	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?
4 5 6 7 8 9 10 11 12 13	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?	3 4 5 6 7 8 9 10 11 12 13	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.
4 5 6 7 8 9 10 11 12 13 14	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD:  Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any
4 5 6 7 8 9 10 11 12 13 14 15 16	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes. Q. And you reference, "now having	3 4 5 6 7 8 9 10 11 12 13 14 15 16	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that
4 5 6 7 8 9 10 11 12 13 14 15 16	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."  A. This number is probably higher	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me? A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."  A. This number is probably higher now, something like 150.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.  Q. Okay. And did your report include
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?  A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."  A. This number is probably higher now, something like 150. Q. Is there a way that you track this	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.  Q. Okay. And did your report include all of the opinions, the basis and the reasons for
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me? A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."  A. This number is probably higher now, something like 150. Q. Is there a way that you track this number?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.  Q. Okay. And did your report include all of the opinions, the basis and the reasons for your opinions that you intend to offer in trial on
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me? A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants." A. This number is probably higher now, something like 150. Q. Is there a way that you track this number? A. When I have time, I sit and then	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.  Q. Okay. And did your report include all of the opinions, the basis and the reasons for your opinions that you intend to offer in trial on these matters?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	form objection.  THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so but I can tell you that I read a lot of clinical studies.  BY MS. BYARD: Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me? A. Yes. Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."  A. This number is probably higher now, something like 150. Q. Is there a way that you track this number?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I could count them quickly, but they are not entered in the spreadsheet.  Q. Okay. I guess I should back up for a second.  Are you fully prepared to discuss all the opinions that are set forth in your report today?  A. Yes.  Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?  A. Yes.  Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?  A. No.  Q. Okay. And did your report include all of the opinions, the basis and the reasons for your opinions that you intend to offer in trial on

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Page 38
                                                                                                          Page 40
                                                             1
 1
      cannot fit in this report. It's just a summary.
                                                                         BY MS. BYARD:
 2
             Q. Are all of the opinions that you
                                                             2
                                                                         Q. Okay. I'd like to look with you,
 3
                                                             3
      intend to offer at trial set forth in this report,
                                                                  and I'll represent to you that these are reports
 4
                                                             4
                                                                  that my expert, Dr. Steven Badylak, put together
      Exhibit 1196?
                                                             5
 5
             A. As I said, there's a summary, yes.
                                                                  based on specimens that he reviewed.
 6
             Q. And you understand that if there
                                                             6
                                                                         And the first is for a woman named
                                                             7
 7
      are updates to this information, that you'll
                                                                  Ellen Hoffman: another is for a woman named Connie
 8
                                                             8
      supplement this through counsel, right?
                                                                  Bennett; and another is for a woman named Deborah
 9
                                                             9
             MR. ORENT: Objection.
                                                                  Kilgore. If you wouldn't mind taking the time to
10
                                                            10
             THE WITNESS: That's correct.
                                                                  just briefly review those.
11
             BY MS. BYARD:
                                                            11
                                                                         MR. ORENT: Let me see those.
                                                            12
12
             Q. Of these 120 samples that -- of
                                                                         THE WITNESS: They look awfully short
13
      transvaginal mesh that you had at least as of the
                                                            13
                                                                  in comparison to mine.
      date that you authored your report and signed it,
                                                            14
14
                                                                         MS. BYARD: There was no question
                                                            15
15
      how many of those had come to you through
                                                                  pending, sir.
16
      Plaintiffs' attorneys?
                                                            16
                                                                         MR. ORENT: I have multiple objections
17
             A. Ratio is somewhat close to
                                                            17
                                                                  to the use of these documents by Dr. Iakovlev.
18
                                                            18
                                                                         Particularly, one, to the extent that
      70 percent. Again, it's approximate ratio.
19
                                                            19
                                                                  this contains information that may relate to the
             Q. Previously when we've deposed you,
                                                            20
20
      you've testified that you didn't know how the
                                                                  private healthcare information of individuals who
21
      Plaintiffs' attorneys selected the specimens that
                                                            21
                                                                  Dr. Iakovlev has not intended to offer any specific
22
                                                            22
      they sent to you; do you recall that?
                                                                  testimonies on.
23
                                                            23
             A. I don't know the specific details,
                                                                         So to the extent that this relates to
24
      but I think it's an irrelevant question, because
                                                            24
                                                                  any protected healthcare information under HIPAA,
25
      nobody knows what's in the specimen unless you look
                                                            25
                                                                  I'm going to place an objection on the record to
                                               Page 39
                                                                                                          Page 41
                                                             1
 1
      in the microscope. So they selected it blindly.
                                                                  that.
 2
              MS. BYARD: Object and move to strike.
                                                             2
                                                                         Second, to the extent that it goes
 3
                                                             3
                                                                  beyond the scope of any of his opinions, I would
              BY MS. BYARD:
 4
              Q. Do you recall having testified
                                                             4
                                                                  object to that.
                                                             5
 5
                                                                         And, I object to asking him to form new
      before that you didn't know how the Plaintiffs'
 6
      attorneys selected the specimens that they sent to
                                                             6
                                                                  opinions on the basis of something that he's never
 7
                                                             7
                                                                  seen before today.
      you?
 8
                                                             8
              MR. ORENT: Wait a minute. Hold on.
                                                                          And third, I'm not sure -- we have
                                                             9
                                                                  multiple questions. These are very new reports,
 9
              He's entitled to a full answer, so we
10
                                                            10
                                                                  and I'm not sure where the specimens originated
      would oppose any motion to strike.
                                                            11
                                                                  from in all of these cases. So subject to those
11
              Go ahead and answer to the extent that
12
      you need to, to make sure that you're offering a
                                                            12
                                                                  objections --
                                                            13
13
      full testimony, full response to the question.
                                                                         MS. BYARD: Has he signed a protective
14
                                                            14
              BY MS. BYARD:
                                                                  order?
                                                            15
15
              Q. My question is whether you
                                                                         MR. ORENT: He has not.
16
      testified before that you didn't know how
                                                            16
                                                                         MS. BYARD: And so how would his review
17
      Plaintiffs' attorneys selected the specimens that
                                                            17
                                                                  of these specimens be any different from the
                                                            18
                                                                  protected health information that you provide to
18
      they gave to you?
19
              MR. ORENT: Objection.
                                                            19
                                                                  him in the form of samples of human tissue?
              THE WITNESS: What was their
                                                            20
                                                                         MR. ORENT: He's retained as an expert
20
                                                           21
21
      methodology? I don't know.
                                                                  and as a treating -- as a physician, he's subject
22
                                                            22
                                                                  to the code of medical ethics.
              But as I said, they selected it blindly
23
      because they couldn't see what's in the specimen.
                                                            23
                                                                         MS. BYARD: Okay.
                                                            24
24
      There's no way of seeing -- I don't know what I'm
                                                                         BY MS. BYARD:
25
      going to find in a specimen before I cross it.
                                                            25
                                                                         Q. Let me just ask you, Doctor, have
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	Page 42		Page 44
1	you reviewed a pathological specimen for Ellen	1	MR. ORENT: And I also
2	Hoffman?	2	MS. BYARD: And you can instruct him as
3	MR. ORENT: And I'm also going to	3	you think prudent.
4	object, because that is to the extent that	4	MR. ORENT: Okay. Just to be clear.
5	you're asking questions whether or not he's been a	5	By allowing us, allowing Dr. Iakovlev to answer
6	disclosed or undisclosed expert, he doesn't need to	6	questions as to his recollection about these
7	answer that question under Rule 26.	7	particular samples, we're not waiving anything in
8	So I'm going to instruct you not to	8	terms of privileges, regarding communications or
9	answer.	9	anything else in those cases, or generally
10	BY MS. BYARD:	10	speaking.
11	Q. Are you going to follow Counsel's	11	BY MS. BYARD:
12	instruction?	12	Q. Let's return to my question then,
13	A. Yes.	13	Doctor, on Ellen Hoffman.
14	Q. Have you reviewed a specimen for	14	Did you review her pathology specimens?
15	Deborah Kilgore?	15	A. I would have to check. (Witness
16	MR. ORENT: I need to consult with the	16	reviews documents.)
17	witness on this.	17	Okay. She is not on this list. There
18	MS. BYARD: Okay. We can go off the	18	is "Hoffman, Lori," but she is not on the list.
19	record.	19	Q. Okay. So
20	THE VIDEOGRAPHER: Off the record at	20	A. But
21	9:50 a.m.	21	Q. You know you didn't issue a report
22	RECESS AT 9:50	22	on Ellen Hoffman?
23	UPON RESUMING AT 9:59	23	MR. ORENT: Objection.
24	THE VIDEOGRAPHER: One moment, please.	24	THE WITNESS: I don't recall. But
25	We're back on the record at 9:59 a.m.	25	again, I don't remember now.
23		23	agam, i dont remember now.
	D 12	1	D 4 E
	Page 43		Page 45
1	MR. ORENT: So, Counsel, and I have	1	BY MS. BYARD:
2	MR. ORENT: So, Counsel, and I have spoken off the record, and I've spoken with	2	BY MS. BYARD: Q. And you can't tell me whether or
2	MR. ORENT: So, Counsel, and I have spoken off the record, and I've spoken with Dr. Iakovlev.	2	BY MS. BYARD: Q. And you can't tell me whether or not you reviewed her pathology or not
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1	instruct the witness not to answer.	1	A. Ask the question again.
2	BY MS. BYARD:	2	Q. You'll acknowledge, though, won't
3	Q. Do you know if there are instances	3	you, that women have excisions following pelvic
4	when counsel had pathological specimens that were	4	surgery, resulting in specimens that don't even
5	never provided to you?	5	contain mesh?
6	A. How would I know that?	6	A. Yes. There are some specimens
7	Q. And returning to Deborah Kilgore,	7	which don't contain mesh.
8	did you review pathology for her?	8	Q. Those were surgeries performed
9	MR. ORENT: Again, subject to my prior	9	because women were experiencing complications,
10	objections.	10	right?
11	THE WITNESS: She's not on the list.	11	MR. ORENT: Objection.
12	BY MS. BYARD:	12	THE WITNESS: Specimens I received
13	Q. And the list that you're referring	13	don't have mesh. But I don't know if they had mesh
14	to, is a list of cases where you have reports that	14	while they were processed in the original
15	have been noticed for the deposition, right?	15	institution.
16	A. Yes. And there are a few more,	16	So what happens, original institution
17	which are not on the list. But I may not recall	17	shaves off subtissue, puts it in the block, and the
18	it. I mean, there is a huge number, like there is	18	mesh is discarded.
19	30. How can I remember all these names?	19	So if it was original excised, and I
20	Q. Okay. You're not looking at a	20	didn't receive it, or it wasn't excised, this, this
21	chain of custody for specimens that have been	21	sometimes is a difficult question.
22	received by your lab, from Steelgate, are you?	22	BY MS. BYARD:
23	A. No, we're not looking at that. I	23	Q. And you don't even know if the
24	could have received some sometimes specimens	24	original institution shaved off the tissue or
25	come dry, and I cannot examine it. Or there is a	25	whether there was even mesh to begin with; correct?
	Page 47		Page 49
			rage 47
1	piece of suture or calcification, something like	1	A. In some cases it's described in
1 2	piece of suture or calcification, something like this. I mean	1 2	A. In some cases it's described in
	•	1	_
2	this. I mean	2	A. In some cases it's described in the pathology report, that they describe mesh; but
2 3	this. I mean Q. Okay.	2 3	A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.
2 3 4	this. I mean Q. Okay. A. Or in some cases, it's not mesh,	2 3 4	A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.  Q. And in other
2 3 4 5	this. I mean Q. Okay. A. Or in some cases, it's not mesh, it's like a uterus or	2 3 4 5	A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.  Q. And in other A. If I have a pathology report.
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2 3 4 5 6 7 8	this. I mean Q. Okay. A. Or in some cases, it's not mesh, it's like a uterus or I think even for uterus, I issued a report but Q. So in some of the pathological	2 3 4 5 6 7 8	A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.  Q. And in other A. If I have a pathology report.  Sometimes I don't have a pathology report.  Q. Now, they use 120 samples that you speak of in your report. Do those include
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2 3 4 5 6 7 8 9	this. I mean Q. Okay. A. Or in some cases, it's not mesh, it's like a uterus or I think even for uterus, I issued a report but Q. So in some of the pathological specimens that you've received, there isn't even any mesh, right? A. In some specimen, yeah, I receive sometimes just a it's mucosa, or scar tissue	2 3 4 5 6 7 8 9	A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.  Q. And in other A. If I have a pathology report.  Sometimes I don't have a pathology report.  Q. Now, they use 120 samples that you speak of in your report. Do those include specimens that you received where you never ultimately issued a report?
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13 (Pages 46 to 49)

Page 50 Page 52 1 So the specimen contains a mesh, and 1 Assuming if I receive three, four 2 it's from vaginal area, then I examine it. If it's 2 specimens for the same patient, I get three, four 3 3 specimen -- sometimes, as I said, I receive a different surgical pathology cases. Or, if two 4 4 uterus. So why would I include the uterus -specimens were excised on the same day, they can be 5 5 findings of a uterus in a spreadsheet which is accessioned as one surgical number with A and B. It 6 depends on the patient. Sometimes it's 1 and 2, research -- which is made for research purposes for 6 7 7 A and B. 8 8 So, are you counting number of cases, So I examined those, I issue report for 9 9 uterus, but then they don't use it for this or are you counting number of patients, or are you 10 10 purpose, research purpose. So it's not listed counting number of meshes? Some patients have 11 there. Or sometimes I receive three, four 11 three meshes. 12 specimens for the same patient. Some of them have 12 Q. How do you log it? 13 sort of piecemeal excision at the same time, or 13 A. We log by surgical number in 14 14 St. Michael's Hospital. So if a specimen comes as excisions are spread during time. 15 15 Q. So for any specimen that you a one, on one single requisition, marked A and B, 16 receive, provided there is mesh, you issue a 16 it becomes one surgical number. Specimen A and 17 pathology report? 17 specimen B. But sometimes I receive them spread in 18 A. Sooner or later, I -- any specimen 18 time, and then the accessioning becomes spread in 19 19 which came in and had to be registered at time, so there are two surgical numbers. 20 St. Michael's Hospital, I issue surgical pathology 20 Or, if I can catch it, when I receive 21 21 it, then I can put it on the same number, just add 22 22 Q. And does that include the it. Again, it's not straightforward sometimes. 23 specimens that you receive through Plaintiff's 23 Q. Okay. We don't have in your 24 counsel? 24 report the number of specimens that you've received 25 25 by surgical number, do we? A. Yes. It doesn't matter if it Page 51 Page 53 1 1 MR. ORENT: Objection. contains a mesh or doesn't contain a mesh, surgical 2 pathology report needs to be issued. I have to 2 THE WITNESS: No. I haven't logged 3 3 sign it out as a diagnostic pathologist, and have them, those. 4 to produce surgical pathology report. 4 BY MS. BYARD: 5 5 Q. So irrespective of whether counsel Q. St. Michael's did, though, didn't 6 ultimately disclosed a report for you in a case, 6 they? 7 you would have logged it when that specimen came in 7 A. I mean, well, they don't count 8 to you at St. Michael's; true? 8 number of specimens received. I can try to do 9 MR. ORENT: Objection. 9 search by words, like "vaginal mesh" or something 10 THE WITNESS: That's true. I cannot do 10 like this. But sometimes they come without 11 staining or I cannot do anything without logging it in. 11 definition of mesh, so accessioning clerk doesn't 12 BY MS. BYARD: 12 know that it's mesh, and it's just entered as 13 13 Q. Okay. And so the 120 number would "tissue." So this would escape search by word. 14 be your number of what -- the number of specimens 14 Q. So today, there's no way for us to 15 that you had received? 15 recreate however many specimens you've received 16 A. 120 --16 through the mesh litigation? 17 17 MR. ORENT: Objection. A. Exact up to single specimen? No, 18 THE WITNESS: 120 is mesh specimens. 18 this would be difficult. 19 19 Those specimens I extracted knowledge about mesh There is no -- I mean, in ballpark, body interactions. 120 is not a log number. 20 20 yes. But, I mean, specifically trace each single 21 BY MS. BYARD: 21 specimen would be hard. Probably chain of custody 22 22 Q. Do you have a log number? forms, this would be easier. But then they are A. It's in St. Michael's information 23 23 spread all over, I mean, from different sources. 24 24 system. And cases are accessioned and they are Q. Do you have copies of all the 25 there. 25 chain of custody forms that you've received, the

14 (Pages 50 to 53)

	Page 54		Page 56
1	specimens you've received through the mesh	1	BY MS. BYARD:
2	litigation?	2	Q. In short, you can't assure to me
3	A. Yes, I do keep copies. But	3	that all of the specimens that are available
4	sometimes chain of custody forms comes in, and then	4	through counsel, had been provided to you, can you?
5	there are three specimens behind it. They put on	5	A. How can I? I mean, I ask for
6	one chain of custody forms, and then next patient	6	everything available. Every time there is a new
7	has three different specimens, which are coming	7	specimens, or a new set of specimens coming out,
8	from three different sources with three different	8	I'm asking for all available medical records and
9	chains of custody.	9	all available specimens.
10	And sometimes chain of custody doesn't	10	Q. Beyond that, you can't assure,
11	specify how many specimens, which shape they came	11	though, that your request has been fulfilled?
12	in. I describe them in surgical pathology report	12	MR. ORENT: Objection.
13	each time I describe the specimen.	13	BY MS. BYARD:
14	Q. Okay. So returning to specimens	14	Q. Can you?
15	where you either haven't reviewed or haven't issued	15	A. No.
16	a report that we know of, this Connie Bennett case	16	Q. Similarly, you can't assure me
17	that I mentioned before; is that one that's	17	that every specimen that you've examined has
18	familiar to you?	18	resulted in a report that's been provided to me,
19	MR. ORENT: Subject to my same	19	can you?
20	objections.	20	MR. ORENT: I'm instructing you not to
21	THE WITNESS: As I said, it's not a	21	answer.
22	memory test. I cannot remember.	22	BY MS. BYARD:
23	I don't remember the name. I may or	23	Q. Okay. Let's continue with this
24	may not have is it on the list?	24	paragraph that we're looking at, if you don't mind,
25		25	Doctor. It says:
	Page 55		Page 57
1	BY MS. BYARD:	1	"My data pool of mesh explant
2	Q. And again, you're looking at the	2	samples contains specimens of
3	list of your reports?	3	St. Michael's Hospital patients,
4	A. Yes. What was the last name?	4	cases sent from outside hospitals,
5	Q. Connie Bennett, B-E-N-N-E-T-T?	5	as well as potential and active
6	A. (Witness reviews document.)	6	litigation cases sent to me as
7	It's not on this list. I could have	7	consultant."
8	issued the report, could have. I don't remember	8	My only question here is on percentages.
9	now.	9	And I think you said you thought close to 70 of the
10	Q. Okay. I'll represent to you,	10	120 listed here were cases that came to you through
11	Doctor, that these three cases are cases where my	11	litigation.
12	expert has received a specimen and issued a report,	12	Do you have updated estimates for me of
13	okay?	13	the number of samples that came from St. Michael's
14		14	Hospital patients and the number sent from other
	All I want to know from you, my		
15	question is whether you can tell me if you either	15	hospitals?
16	question is whether you can tell me if you either didn't receive specimens for these women; or, a	15 16	hospitals?  MR. ORENT: Objection. I just want to
16 17	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never	15 16 17	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.
16 17 18	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?	15 16 17 18	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD:
16 17 18 19	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the	15 16 17 18 19	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD:  Q. Oh, did you say 70?
16 17 18 19 20	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the witness not to answer those questions.	15 16 17 18 19 20	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD:  Q. Oh, did you say 70?  A. Yes, 70 percent.
16 17 18 19 20 21	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the witness not to answer those questions.  THE WITNESS: As per my counsel	15 16 17 18 19 20 21	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD: Q. Oh, did you say 70? A. Yes, 70 percent. Q. Oh, thank you.
16 17 18 19 20 21 22	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the witness not to answer those questions.  THE WITNESS: As per my counsel MS. BYARD: Are you going to follow	15 16 17 18 19 20 21 22	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD: Q. Oh, did you say 70? A. Yes, 70 percent. Q. Oh, thank you. A. Roughly 70 percent, I think. It's
16 17 18 19 20 21 22 23	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the witness not to answer those questions.  THE WITNESS: As per my counsel MS. BYARD: Are you going to follow your counsel?	15 16 17 18 19 20 21 22 23	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD: Q. Oh, did you say 70? A. Yes, 70 percent. Q. Oh, thank you. A. Roughly 70 percent, I think. It's an estimate.
16 17 18 19 20 21 22	question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?  MR. ORENT: I'm going to instruct the witness not to answer those questions.  THE WITNESS: As per my counsel MS. BYARD: Are you going to follow	15 16 17 18 19 20 21 22	hospitals?  MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.  BY MS. BYARD: Q. Oh, did you say 70? A. Yes, 70 percent. Q. Oh, thank you. A. Roughly 70 percent, I think. It's

	Page 58		Page 60
1	A. I mean, 70 from litigation and 30,	1	of mesh, or more of a raw mesh.
2	about 30 non-litigation.	2	(Reporter sought clarification.)
3	Q. So 30 either from St. Michael's or	3	A. Raw material, raw material of the
4	from outside hospitals?	4	mesh. It's not formal device.
5	A. It's mainly St. Michael's. For	5	Q. Is the Prefyx a sling, or is it
6	transvaginal, it's mainly St. Michael's Hospital.	6	indicated for the treatment of pelvic organ
7	Q. For the outside hospitals, do you	7	prolapse?
8	know how they select which samples they give to you	8	A. Prefyx, I'm not sure about this
9	and which they don't?	9	one.
10	A. Those clinicians, they just send	10	Q. How about the Advantage Fit?
11	whatever is available, consecutive.	11	A. Advantage is I would have to
12	(Reporter sought clarification.)	12	check. I mean, it's not a memory test. Every time
13	A. Consecutive.	13	I see some name I'm not sure, I just Google and
14	Q. But if there are samples that they	14	check with Boston Scientific website.
15	don't send to you, you wouldn't know about that one	15	Q. Sitting here today, though, you
16	way or the other, would you?	16	can't tell me?
17	A. No.	17	MR. ORENT: Objection.
18	MR. ORENT: Objection.	18	THE WITNESS: I wouldn't guess. I
19	BY MS. BYARD:	19	don't want to guess.
20	Q. Okay. Turning to the next page,	20	BY MS. BYARD:
21	the first full paragraph.	21	Q. What about Uphold? Is that
22	And I'm on page 3 of 1196 for the	22	indicated for stress urinary incontinence or for
23	record?	23	pelvic organ prolapse?
24	A. Yes.	24	A. Pelvic organ prolapse.
25	Q. You talk about how pathologists	25	Q. How many incisions are used to
	Page 59		Page 61
1	Page 59		Page 61
1	are trained and develop skills for subjective	1	place a Solyx?
2	are trained and develop skills for subjective assessments?	2	place a Solyx?  A. It's a clinical question. I'm not
2 3	are trained and develop skills for subjective assessments?  A. That's correct.	2 3	place a Solyx?  A. It's a clinical question. I'm not a clinician.
2 3 4	are trained and develop skills for subjective assessments?  A. That's correct. Q. You write that:	2 3 4	place a Solyx?  A. It's a clinical question. I'm not a clinician.  Q. Where is the incision or incisions
2 3 4 5	are trained and develop skills for subjective assessments?  A. That's correct. Q. You write that: "To understand the related	2 3 4 5	place a Solyx?  A. It's a clinical question. I'm not a clinician.  Q. Where is the incision or incisions located?
2 3 4 5 6	are trained and develop skills for subjective assessments?  A. That's correct. Q. You write that: "To understand the related pathological processes and make a	2 3 4 5 6	place a Solyx?  A. It's a clinical question. I'm not a clinician.  Q. Where is the incision or incisions located?  MR. ORENT: Objection.
2 3 4 5 6 7	are trained and develop skills for subjective assessments?  A. That's correct. Q. You write that: "To understand the related pathological processes and make a correct diagnosis, pathologists need	2 3 4 5 6 7	place a Solyx?  A. It's a clinical question. I'm not a clinician.  Q. Where is the incision or incisions located?  MR. ORENT: Objection.  THE WITNESS: For which type?
2 3 4 5 6 7 8	are trained and develop skills for subjective assessments?  A. That's correct. Q. You write that:  "To understand the related pathological processes and make a correct diagnosis, pathologists need to understand the function of the	2 3 4 5 6 7 8	place a Solyx?  A. It's a clinical question. I'm not a clinician.  Q. Where is the incision or incisions located?  MR. ORENT: Objection.  THE WITNESS: For which type?  BY MS. BYARD:
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16 (Pages 58 to 61)

	Page 62		Page 64
1	A. Which go through skin, so there	1	Q. So it's your testimony that the
2	you need to make an incision in the skin. But then	2	treatment modalities wouldn't differ depending on
3	it's not an incision linear.	3	whether a pudendal nerve branch versus another
4	Q. Where does the what you're	4	nerve branch were ingrown in mesh?
5	calling the trocar track, or the trocar pass,	5	A. No.
6	compare in location for an Obtryx versus retropubic	6	MR. ORENT: Objection.
7	sling, for instance?	7	BY MS. BYARD:
8	MR. ORENT: Objection.	8	Q. The reality is that you don't
9	THE WITNESS: A retropubic sling	9	treat clinical complications from pelvic mesh, do
10	doesn't go into a transobturator. So the arms go	10	you?
11	retropubically, pointing upward. So it's	11	MR. ORENT: Objection.
12	BY MS. BYARD:	12	THE WITNESS: No.
13	Q. Where do the incisions for the	13	BY MS. BYARD:
14	trocar tracks let me start over.	14	Q. And so you don't need to
15	How do the incisions for the trocar	15	understand, as a pathologist, from your
16	tracks or passes for the Obtryx sling compare to	16	perspective, whether or not the nerve that you see
17	the Advantage sling?	17	is a pudendal nerve, or part of an obturator nerve,
18	MR. ORENT: Objection.	18	or part of the genital femoral nerves, right?
19	THE WITNESS: I think we are going	19	A. I think you're misrepresenting.
20	beyond the scope of what pathologists need to	20	You're talking about large nerves, large branches
21	understand.	21	so which have names. There will be thousands of
22	I need to understand if the sling is	22	other smaller branches, which don't have names.
23	placed in specific anatomical area, and what	23	So you're making it kind of like a
24	anatomical spaces are displaced. Specific details	24	cartoon, more of a reality is different. The
25	of surgical techniques need to be understood only	25	genital area is very richly innervated, nerves
	Page 63		Page 65
1	to a degree, which helps me to understand the	1	coming from different places. You're talking about
2	function.	2	large nerve, but the branches have no names, and
3	So you're asking me very specific	3	then they go in the area. So it's either you have
4	details which would be important for a clinician,	4	a misunderstanding, or just trying to make it look
5	but as a pathologist, they are not as important to	5	like this.
6	me. So, I think we're going beyond what I would	6	MS. BYARD: Object and move to strike.
7	need to know.	7	MR. ORENT: Oppose.
8	BY MS. BYARD:	8	BY MS. BYARD:
9	Q. Well, would the Obtryx device or	9	Q. Does the Uphold fix to any
10	the Uphold device pass closer to the pudendal	10	specific anatomical structures in the female
11	nerve?	11	pelvis?
12	MR. ORENT: Objection.	12	MR. ORENT: Objection.
13	THE WITNESS: Obtryx or Uphold. I	13	THE WITNESS: What do you mean "fixed"?
14	cannot tell you which one would be closer. Again,	14	By stitches?
15	this would be irrelevant, because I see nerve	15	BY MS. BYARD:
16	ingrowth in both, and it doesn't matter if it's	16	Q. Sure.
17	coming from a pudendal nerve or any other nerve or	17	A. No, there are no stitches.
18	smaller branch.	18	Q. Is it affixed to any other
19	BY MS. BYARD:	19	anatomical landmarks in the pelvis?
20	Q. Does it matter for a patient's	20	MR. ORENT: Objection. Scope.
21	clinical symptomology whether or not there's	21	THE WITNESS: I have to ask questions,
22	involvement of the pudendal nerve versus other	22	how it is fixed? I mean, is it fixed by stitching,
		23	or it's fixed by ingrowth?
23	nerves?		· ·
23 24	A. What matters is involvement of a	24	BY MS. BYARD:

17 (Pages 62 to 65)

1	Page 66		Page 68
1	A. Specifically, the meshes are not	1	THE WITNESS: I mean, you're asking me
2	stitched to tissues. So they mainly depend on	2	questions which clearly are clinical questions.
3	tissue ingrowth.	3	BY MS. BYARD:
4	Q. How about fixed by placement to	4	Q. Okay.
5	any of the anatomical structures of the pelvis? Do	5	A. As I said, as a pathologist I need
6	you know whether that occurs?	6	to understand what the device looks like, what is
7	MR. ORENT: Objection.	7	it made from, and what anatomical location it is
8	THE WITNESS: What do you mean, "fixed	8	placed, what is its function.
9	by placement"?	9	That's as much that's, basically,
10	Placement is just you place something.	10	generally what I need to know. You're going to
11	BY MS. BYARD:	11	somewhere where it's completely beyond my scope, my
12	Q. What is the Capio?	12	expertise.
13	A. Pardon?	13	Q. You write in your report that you
14	Q. The Capio?	14	need to understand the function of the devices
15	A. I don't know what you're talking about.	15	being analyzed, right?
16	MR. ORENT: Objection. Scope.	16	A. Yes.
17	BY MS. BYARD:	17	Q. You write that you need to know
18	Q. Do Boston Scientific's pelvic mesh	18	the devices' physical characteristics, right?
19	products make use of trocars?	19	MR. ORENT: Objection. These are
20	MR. ORENT: Objection. Vague. Form.	20	THE WITNESS: The functions for stress
21	Scope.	21	urinary incontinence is to support urethra.
22	THE WITNESS: What do you mean?	22	Physical characteristics, I see it's a
23	BY MS. BYARD:	23	polypropylene, it's not biological mesh. That's
24	Q. You used the word "trocars"	24	what I'm talking about.
25	before. What did you mean by that?	25	what I in tarking about.
23	· · ·	23	
-	Page 67		Page 69
1	A. It's a device which comes in the	1	BY MS. BYARD:
2	kit. It's more of like a long needle.		0 01 D ( 1 1
		2	Q. Okay. But as far as where these
3	Q. Do Boston Scientific's pelvic	3	devices pass in the anatomy, based on their
4	organ prolapse kits make use of trocars?	3 4	devices pass in the anatomy, based on their surgical placement, you haven't been able to tell
4 5	organ prolapse kits make use of trocars?  MR. ORENT: Objection.	3 4 5	devices pass in the anatomy, based on their surgical placement, you haven't been able to tell me that with specificity, because those are better
4 5 6	organ prolapse kits make use of trocars?  MR. ORENT: Objection.  THE WITNESS: Yes, they're included in	3 4 5 6	devices pass in the anatomy, based on their surgical placement, you haven't been able to tell me that with specificity, because those are better questions for a clinician; correct?
4 5 6 7	organ prolapse kits make use of trocars?  MR. ORENT: Objection.  THE WITNESS: Yes, they're included in the kits.	3 4 5 6 7	devices pass in the anatomy, based on their surgical placement, you haven't been able to tell me that with specificity, because those are better questions for a clinician; correct?  A. No
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	organ prolapse kits make use of trocars?  MR. ORENT: Objection.  THE WITNESS: Yes, they're included in the kits.  BY MS. BYARD: Q. Doctor, if I asked you to describe how you perform a Kelly plication, would you be able to do that?  MR. ORENT: Objection. Outside the scope.  THE WITNESS: I'm a pathologist. I don't do  BY MS. BYARD: Q. Okay. Same thing for perineorrhaphy? MR. ORENT: Objection. And similarly, I think these questions are designed to embarrass or offend the witness.  MS. BYARD: No. I'm asking the questions I need to ask, John. So I object to the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	devices pass in the anatomy, based on their surgical placement, you haven't been able to tell me that with specificity, because those are better questions for a clinician; correct?  A. No MR. ORENT: Objection. THE WITNESS: this is not correct.  I know where they are placed. You are asking me how they are placed, and this is the difference. Because I don't need to know exact very specific details how they are placed. But, in general, where they are placed and what anatomical sort of locations are they placed that's generally what I need to understand.  If I need very specific questions, if there is a very specific question for specific diagnostic procedure, then I would go and consult with clinician. Like a placement of a stent, which artery it was placed in the heart, was it LED or it was circumflex? I mean, these would be very

18 (Pages 66 to 69)

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Page 70
                                                                                                        Page 72
 1
      and other things. I mean, I receive specimen six
                                                            1
                                                                        edema within mesh compartments, as
 2
      years later when all incisions are healed.
                                                            2
                                                                        well as innervation with nerve
 3
                                                            3
                                                                        ingrowth into the mesh compartments,
              BY MS. BYARD:
                                                            4
                                                                        vascular abnormalities and mesh
 4
              O. Does the location of the incision
                                                            5
 5
      help you understand where the device was
                                                                        degradation."
      anatomically located when it was actually in the
                                                            6
                                                                        Did I read that all reasonably
 6
 7
      patient's body?
                                                            7
                                                                 correctly?
                                                            8
 8
              A. It can be very long way from
                                                                        A. That's correct.
 9
      incision to the placement of the device. So it may
                                                            9
                                                                        Q. How do you define chronic
10
                                                          10
      or may not help, but most of the time --
                                                                 lymphoplasmacytic --
11
             For example, if it's a hernia, if it's
                                                          11
                                                                        A. Cytic.
12
      open hernia, I know that there was incision from
                                                          12
                                                                        Q. -- cytic inflammation composed of
13
      skin. So it's open hernia surgery.
                                                          13
                                                                 foreign body reaction?
14
                                                          14
             If it's laparoscopic, I know that the
                                                                        A. Foreign body reaction, as I
      access was laparoscopically. So it's a different
                                                          15
                                                                 explained before, is a collection of epithelioid
15
16
      anatomical location. So a laparoscopic hernia
                                                          16
                                                                 histiocytes, these are mononucleated or
17
      would be more of an intraperitoneal access. That
                                                          17
                                                                 multinucleated. Lymphoplasmacytic, as the word
18
      makes a difference.
                                                          18
                                                                 implies, is lymphocytes and plasma cells.
19
                                                          19
              If you put sling through incision one
                                                                        Q. How do you define vascular
20
      centimeter to the left or right, it will not make a
                                                          20
                                                                 congestion?
21
      difference.
                                                          21
                                                                        A. If the vessels are enlarged, then
22
                                                          22
              O. So whether --
                                                                 fully packed with red blood cells.
23
              A. But it might make a difference for
                                                          23
                                                                        Q. What did you mean by "vascular
24
      a surgeon.
                                                          24
                                                                 abnormalities"?
25
                                                          25
              Q. So whether or not the sling is
                                                                        A. I see obliterated arteries. I see
                                                                                                        Page 73
                                              Page 71
      placed in the retropubic space as opposed to
                                                                 thrombosed capillaries.
 1
                                                            1
 2
      through the transobturator space doesn't make a
                                                            2
                                                                        Q. And for a lay person, what does
 3
      difference to you as a pathologist?
                                                            3
                                                                 obliterated arteries and thrombose capillaries
 4
              A. It does make a difference.
                                                            4
                                                                 mean?
                                                            5
 5
              As I said, this is an anatomical
                                                                        A. A vessel which doesn't supply
 6
      location, that's what I'm -- I try to understand
                                                            6
                                                                 blood anymore.
 7
      every time I encounter a new device. But how it
                                                            7
                                                                        Q. Are you able to tell,
 8
      was placed specifically, all intricate details of
                                                            8
                                                                 microscopically, when that obliteration occurred?
      surgical techniques, they're irrelevant for this.
                                                            9
                                                                        A. To a certain degree.
 9
              Q. Moving to the third paragraph, the
                                                          10
10
                                                                        O. How so?
                                                          11
11
      third full paragraph on page 3, please, Doctor.
                                                                        A. Sometimes I can say that it's been
12
                                                          12
                                                                 week or even month, maybe years, or sometimes it's
              A. Yes.
                                                          13
13
              Q. You write that you have been able to:
                                                                 a relatively recent event, days. Or hours.
14
                 "Directly observe changes in
                                                          14
                                                                        Q. But how do you discern that
15
              the mesh samples, including but not
                                                          15
                                                                 microscopically, I think was my question?
16
              limited to scar encapsulation, scar
                                                          16
                                                                        A. Oh, then I would have to give you
                                                          17
17
              maturation with contraction, the
                                                                 a lecture. Vital response, the stages of tissue
18
              inflammatory response to the
                                                          18
                                                                 reacting to a blocked vessel.
                                                          19
19
              implanted mesh, including but not
                                                                        First, inflammatory cells, then there
                                                          20
                                                                 would be changes in the vascular wall, organization
20
              limited to the foreign body reaction
21
              and chronic lymphoplasmacytic
                                                          21
                                                                 of the thrombus, recolonization.
22
              inflammation --"
                                                          22
                                                                        Q. And so when you say you observe an
23
              A. Plasmacytic.
                                                          23
                                                                 obliterated artery, for instance, would you
                                                          24
24
              Q. Thank you.
                                                                 typically, as a pathologist, record whether or not
25
                 "-- vascular congestion and
                                                          25
                                                                 you saw these tissue reactions to the inciting
```

19 (Pages 70 to 73)

	Page 74		Page 76
1	event?	1	Carey and Dr. John Steege, "Pathology of Explanted
2	A. Depends on clinical relevance.	2	Transvaginal Meshes," International Journal of
3	For example, if there is autopsy case	3	Medical Health, Pharmaceutical and Biomedical
4	and I see that the arteries in the heart is	4	Engineering, 2014; is that right?
5	obliterated, it will depend. If it's an old	5	A. Correct.
6	injury, definitely it wasn't cause of death. If	6	Q. The second is an article published
7	it's fresh injury, this can be cause of death.	7	with Dr. Bendavid, Dr. Lou and Koch, "Mesh-Related
8	This is just an example.	8	SIN Syndrome: A Surreptitious, Irreversible
9	Q. And what is thrombosed capillary?	9	Neuralgia and Its Morphologic Background in the
10	What does that term mean for a lay person?	10	Etiology of Post-Herniorrhaphy Pain," International
11	A. Capillaries doesn't supply blood	11	Journal of Clinical Medicine, 2014.
12	anymore.	12	These are both full published articles,
13	Q. Turning to your list of articles	13	right?
14	that you've set forth here, this list, did you	14	A. Yes, these are full articles.
15	intend it to include all of your publications,	15	Q. And then we have a list of
16	abstracts, lectures, oral and poster presentations	16	abstracts. And there's five listed here, right?
17	pertinent to the subject of your report?	17	A. No, there are more. They're all
18	A. Pertinent to my mesh research, yes.	18	included on the flash drive.
19	Q. Okay. All of these are from 2014,	19	Q. There are five listed here, right?
20	right?	20	A. On this page, yes, there are five.
21	A. Yes.	21	Q. How many more are there on that
22	Q. I'd like to	22	thumb drive?
23	A. Just one was earlier. When we	23	A. Maybe a couple. I don't remember now.
24	started	24	Q. And you put this list together
25	Q. Oh, yes. "The Pathological	25	sometime around November 10th, 2014, right?
	Page 75		Page 77
1	Findings in Explanted Surgical Meshes," that	1	A. October, November, yeah.
2	presentation	2	Q. So the abstracts that are you
3	A. Yes.	3	have on your thumb drive, the abstracts that are in
4	Q that you gave?	4	addition to this list that are available on this
5	A. The work, as I said, started in 2012.	l _	
6		5	thumb drive, were published since November 10th of
_	Q. For hernia mesh, right?	5 6	thumb drive, were published since November 10th of 2014?
7	<ul><li>Q. For hernia mesh, right?</li><li>A. Yeah. I think I received first</li></ul>	1	_
-	A. Yeah. I think I received first transvaginal mesh very soon, January or February	6	2014? A. Either published or presented. So I usually put something published or presented on
7	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been	6 7 8 9	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted.
7 8	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is	6 7 8	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay.
7 8 9 10 11	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is I don't remember now.	6 7 8 9 10 11	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay. A. But sometimes depends. Sometimes
7 8 9 10 11 12	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is I don't remember now.  Q. Yeah, but 2013?	6 7 8 9 10 11 12	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay. A. But sometimes depends. Sometimes I put something that has been accepted, but hasn't
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7 8 9 10 11 12 13 14 15	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is I don't remember now.  Q. Yeah, but 2013?  A. All in 2013, yes. Q. Okay. All of these publications, though, with the exception of this oral	6 7 8 9 10 11 12 13 14	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay. A. But sometimes depends. Sometimes I put something that has been accepted, but hasn't been presented. Q. Let's look at these five abstracts. The first one is published by you and
7 8 9 10 11 12 13 14 15	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is I don't remember now.  Q. Yeah, but 2013? A. All in 2013, yes. Q. Okay. All of these publications, though, with the exception of this oral presentation, are from 2014, right?	6 7 8 9 10 11 12 13 14 15	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay. A. But sometimes depends. Sometimes I put something that has been accepted, but hasn't been presented. Q. Let's look at these five abstracts. The first one is published by you and Dr. Mekel and Blaivas?
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7 8 9 10 11 12 13 14 15 16 17 18	A. Yeah. I think I received first transvaginal mesh very soon, January or February of or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is I don't remember now.  Q. Yeah, but 2013?  A. All in 2013, yes. Q. Okay. All of these publications, though, with the exception of this oral presentation, are from 2014, right?  A. Yes. Most of the work was done completed in 2014.	6 7 8 9 10 11 12 13 14 15 16 17	A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted. Q. Okay. A. But sometimes depends. Sometimes I put something that has been accepted, but hasn't been presented. Q. Let's look at these five abstracts. The first one is published by you and Dr. Mekel and Blaivas? A. That's correct. Q. "Pathological Findings of
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20 (Pages 74 to 77)

	Page 78		Page 80
1	Mesh Products: A Biomaterials Perspective Using	1	presentations forms of the articles and abstracts?
2	Materials Science Fundamentals," 2014.	2	A. Not all of them. For the Canadian
3	A. That's correct.	3	hernia meetings, I was just invited to come without
4	Q. Number three is Vladimir Iakovlev:	4	abstracts.
5	"Explanted Surgical Meshes: What Pathologists and	5	Q. Okay. Can you point those out to me?
6	Industry Failed to Do for 50 Years," 2014, right?	6	A. This, number one.
7	A. That's correct.	7	Q. Okay.
8	Q. Yourself, Dr. Guelcher and	8	A. (Witness reviews document.)
9	Dr. Bendavid: "In-vivo Degradation of Surgical	9	This was just an invitation. Number
10	Polypropylene Meshes: A Finding Overlooked for	10	three, also just an invitation. Number five
11	Decades," 2014. Right?	11	Q. Okay.
12	A. That's correct.	12	A this was just an invitation.
13		13	
14	Q. Number five is an abstract with	14	Yup.
	yourself, Dr. Erin Teeter Carey, Dr. Iakovleva		MR. ORENT: When we get to a good
15	A. Yes.	15 16	breaking point, we can take our first break.
16	Q Dr. Steege and Dr. Bendavid:		MS. BYARD: Now is a fine time for me.
17	"Pathological Findings Associated with Pain in	17	MR. ORENT: Okay.
18	Transvaginal Meshes."	18	THE VIDEOGRAPHER: This marks the
19	A. That's correct.	19	end of media number one, in the deposition of
20	Q. 2014.	20	Dr. Vladimir Iakovlev.
21	And then you list here some lectures	21	We're going off the record at 10:43 a.m.
22	and oral presentations.	22	RECESS AT 10:43
23	This first one, is a copy of that	23	EXHIBIT NO. 1197: Article entitled,
24	included in materials that you've provided on the	24	"Mesh-Related SIN Syndrome: A
25	thumb drive?	25	Surreptitious Irreversible Neuralgia
	Page 79		Page 81
1	A. Yes. I included all what I could	1	and Its Morphologic Background in the
2	at this stage, I mean, whatever I had.	2	Etiology of Post-Herniorrhaphy Pain,"
3	Q. Okay. And number two, is that	3	International Journal of Clinical
4	essentially a duplication of the fully published	4	Medicine, 2014, by Dr. R. Bendavid,
5	article number one on your list?	5	Dr. W. Lou, Dr. A. Koch and Dr. V.
6	A. Well, it's a duplication of the	6	Iakovlev.
7	title. So what happens with some conferences or	7	UPON RESUMING AT 11:03
8	other meetings, it's a bit an abstract. Abstract	8	THE VIDEOGRAPHER: Here begins media
9	is accepted, it's published either in special	9	number two in the deposition of Dr. Vladimir
10	journal issue, and then they make a decision, if	10	Iakovlev.
11	· · · · · · · · · · · · · · · · · · ·		
12	you make an oral presentation, or you make a poster	11	We're back on the record at 11:03 a.m.
	·	11 12	We're back on the record at 11:03 a.m. BY MS. BYARD:
13	you make an oral presentation, or you make a poster		
13 14	you make an oral presentation, or you make a poster presentation.	12	BY MS. BYARD:
	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral	12 13	BY MS. BYARD: Q. Doctor, I'll hand you what's been
14	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because	12 13 14	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel.
14 15	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review	12 13 14 15	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you.
14 15 16	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you	12 13 14 15 16	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD:
14 15 16 17	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.	12 13 14 15 16 17	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197?
14 15 16 17 18	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.  So it becomes presented twice. One in	12 13 14 15 16 17 18	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes.
14 15 16 17 18 19	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.  So it becomes presented twice. One in the form of abstract, and then one in the form of	12 13 14 15 16 17 18 19	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes. Q. What is it?
14 15 16 17 18 19 20	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.  So it becomes presented twice. One in the form of abstract, and then one in the form of presentation. Either oral presentation or poster	12 13 14 15 16 17 18 19 20	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes. Q. What is it? A. It's published article,
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14 15 16 17 18 19 20 21	you make an oral presentation, or you make a poster presentation.  So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.  So it becomes presented twice. One in the form of abstract, and then one in the form of presentation. Either oral presentation or poster presentation.  Q. Okay. So for all these articles	12 13 14 15 16 17 18 19 20 21 22	BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes. Q. What is it? A. It's published article, co-authored by me. Q. So these other doctors listed on

21 (Pages 78 to 81)

	Page 82		Page 84
1	Q. Do these doctors use mesh and	1	A. That's correct.
2	hernia repair, to your knowledge?	2	Q. Would you describe this study as
3	A. Yes. Except for Dr. Lou, she's a	3	having been controlled through the use of virgin
4	statistician.	4	tissue and scar tissue?
5	Q. Presently Dr. Bendavid continues	5	A. No. As I said, control is a
6	to use polypropylene mesh for the treatment of	6	specific statistical term for clinical prospective
7	abdominal hernia repair; correct?	7	studies.
8	MR. ORENT: Objection.	8	Q. How would you describe this study
9	THE WITNESS: No. Actually, he uses	9	then?
10	native tissue to repair. He takes out meshes.	10	A. This was a prospective study.
11	BY MS. BYARD:	11	Q. Why was it important for the study
12	Q. Did there come a time when his	12	to use virgin tissue, scar tissue, and explanted
13	practice changed in that regard, to your knowledge?	13	mesh specimens in comparison to one another?
14	A. It depends. I mean, in some	14	A. There were two questions. First
15	patients you just have no choice. You have to use,	15	question was, if nerve ingrowth occurs in the mesh
16	like, um, central large defects.	16	which has been reported even before this paper.
17	Q. So he makes a patient your	17	And the second question was, what's the
18	understanding is that Dr. Bendavid makes a	18	nerve density in comparison with virgin tissue and
19	patient-specific determination about whether or not	19	scar without mesh. If mesh inhibits nerve
20	to use polypropylene mesh in hernia repair?	20	ingrowth; and if it inhibits, to what degree. Sort
21	MR. ORENT: Objection.	21	of establishes a baseline for these parameters.
22	THE WITNESS: That's correct.	22	Q. So you used virgin tissue and scar
23	BY MS. BYARD:	23	tissue in order to establish a baseline for the
24	Q. Is the same true for Dr. Andreas	24	comparison to mesh that you were making in terms of
25	Koch?	25	nerve proliferation in tissue, correct?
	Page 83		Page 85
1			
1 +	A. Koch.	1	A. Mesh and scar were more of a
2	A. Koch. MR. ORENT: Objection.	1 2	A. Mesh and scar were more of a controls in this study. I mean virgin, was more of
	A. Koch. MR. ORENT: Objection. BY MS. BYARD:	1	controls in this study. I mean virgin, was more of
2	MR. ORENT: Objection.	2	
2	MR. ORENT: Objection. BY MS. BYARD:	2 3	controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.
2 3 4	MR. ORENT: Objection. BY MS. BYARD: Q. Koch? A. Yes.	2 3 4	controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.  Q. So explain to the jury what you
2 3 4 5	MR. ORENT: Objection. BY MS. BYARD: Q. Koch?	2 3 4 5	controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.
2 3 4 5 6	MR. ORENT: Objection. BY MS. BYARD: Q. Koch? A. Yes. Q. Okay. Explain to the jury what a	2 3 4 5 6	controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.  Q. So explain to the jury what you mean by "control".
2 3 4 5 6 7	MR. ORENT: Objection. BY MS. BYARD: Q. Koch? A. Yes. Q. Okay. Explain to the jury what a controlled study is.	2 3 4 5 6 7	controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.  Q. So explain to the jury what you mean by "control".  MR. ORENT: Objection.
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22 (Pages 82 to 85)

Page 86 Page 88 1 scar tissue. So control for scar around and inside 1 for nerve density, nerve size, and nerve and vessel 2 the mesh would be scar without mesh. So the same 2 ingrowth, correct? 3 3 area, surgical procedure, all of those are A. That's correct. Well, we assessed 4 4 variables are the same, except one group has mesh the specimen, so we observed what was abnormal in 5 5 and the other group doesn't have mesh. the microscope. So the main hypothesis and main 6 б focus was nerve ingrowth, but then there were other Q. Other terms that are used to 7 7 microscopic findings within mesh specimens which describe study designs include "randomized studies" 8 8 or "blinded studies"; are you familiar with those were observed. 9 9 terms? Q. You found that there were no 10 A. Yes, I am. 10 significant differences in nerve density between 11 Q. Is it fair to say that this was a 11 virgin scar and mesh samples, correct? 12 12 controlled study, but not randomized or blinded? A. Yeah, that's correct. In that 13 A. You're just using it in different --13 sample size, there was no statistical significant 14 14 randomized, controlled studies -- these are all difference. 15 15 clinical terms, specific statistical methods for Q. You concluded that the presence of 16 16 clinical prospective studies when a drug is tested mesh does not significantly affect nerve density, 17 or a new device is tested. So the patients are 17 18 18 randomized before they are given treatment. And A. It's the same statement as before. 19 19 then they follow this cohorts. And then there is Q. You concluded that -- you 20 statistical methods to follow that, and there are 20 concluded, though, that the nerves and their 21 specific requirements for that. 21 terminal ends were in a volnerable position about 22 22 In this case, it's not applicable, the mesh and within its pores? 23 because there were no new device, no new medication 23 A. That was additional findings, 24 introduced. And the randomization is done before 24 because we observed changes of the scar tissue 25 the device is being inserted, or new medication is 25 within the mesh, because it was different from the Page 87 Page 89 1 1 scar without the mesh. given. You cannot randomize it after. So it's 2 2 completely different, we are talking about Q. How so? 3 completely different scenarios. 3 A. It's all described in the paper. 4 4 Q. Well, and it wasn't blinded in the There are vascular congestion, edema, inflammation, 5 5 foreign body type, chronic lymphoplasmacytic sense that you knew whether the specimen that you 6 were looking at was native tissue or virgin tissue, 6 inflammation. 7 7 whether it was scar tissue or whether it was mesh, (Reporter sought clarification.) 8 8 A. Foreign body type inflammation, correct? 9 and chronic lymphoplasmacytic inflammation. 9 A. Blinded, again, it's more of a 10 MR. ORENT: L-Y-M-P-H-O-P-L-A-S-M-A-C-Y-T-I-C 10 clinical terminology when you do controlled 11 BY MS. BYARD: 11 studies. 12 Q. What did you mean by "in a 12 So either patients are blinded, or 13 vulnerable position"? 13 researchers are blinded. I mean, there was a 14 14 A. In a pathologically changed degree of blindness in this study. But again, 15 15 talking about completely different statistical tissue, mainly it is compartmentalization of the 16 16 scenarios, completely different approaches. mesh. So what happens, the scar tissue within the 17 mesh is divided into compartments. So, 17 Q. What do you mean by, there was a 18 essentially, there are little gates or bottlenecks 18 degree of blinded in this study? 19 in the mesh. And this mainly causes the problem. 19 A. When I was examining them, I was 20 Because it's compartment, it's enclosed 20 examining them without knowledge of other clinical 21 21 variables. I could clearly see that there's no compartment. Like tooth pulp, this is best 22 22 analogy. It gets inflamed; you feel pain. mesh in it; if it's scar or not scar. 23 23 Q. You didn't write here, though, But then I didn't know if there were 24 2.4 that the compartmentalization of nerves in mesh is comorbidities, other possible clinical variables. 25 Q. So here you examined the samples 25 what caused clinical complications in these

23 (Pages 86 to 89)

	Page 90		Page 92
1	patients. You wrote that they were in a vulnerable	1	what I think is well, usually, it is what is
2	position, correct?	2	available.
3	A. In the text, I think there is	3	If it's a large POP device, I submit
4	compartmentalization discussion.	4	representative sections. Usually not more than
5	Q. Well, what you wrote, though, was	5	three blocks. I never needed to submit more
6	that nerve receptors were exposed to potential	6	tissue. Either I submitted everything, or it was
7	mechanical and chemical factors: Scarring,	7	satisfactory for examination to submit what I
8	entrapment, compression, tugging, deformation,	8	submitted first time.
9	contraction, hypoxia/acidosis, inflammation and	9	BY MS. BYARD:
10	edema. That's what you wrote; correct?	10	Q. What do you mean by
11	A. That's an abstract.	11	"representative sections"?
12	MR. ORENT: Objection.	12	A. Representative of the sample.
13	THE WITNESS: You're reading an	13	Q. And how do you determine that?
14	abstract. I'm saying that there is discussion	14	A. According to my training and
15	longer in the text.	15	experience.
16	BY MS. BYARD:	16	Q. Are you taking, though, when you
17	Q. Is that what appears in the	17	examine transvaginal mesh specimens, are you taking
18	abstract, sir?	18	samples or sections that you determine are
19	A. You just read it, yes.	19	representative based on your training?
20	Q. In the introduction, the last	20	A. Yes.
21	sentence reads:	21	MR. ORENT: Objection.
22	"The mesh in question is	22	BY MS. BYARD:
23	polypropylene, the most widely used	23	Q. In the second full paragraph under
24	polymer in hernia repair." Correct?	24	methods you write:
25	A. That's correct.	25	"If a peripheral nerve was seen
23		23	<u> </u>
	Page 91		Page 93
1	Q. There's a discussion here under	1	an imaginary line connecting the
2	Q. There's a discussion here under your methods, that the mesh samples	2	an imaginary line connecting the outermost points of adjacent mesh
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2 3 4	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and	2 3 4	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore."
2 3 4 5	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not	2 3 4 5	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right?
2 3 4 5 6	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two	2 3 4 5 6	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. There's a discussion here under your methods, that the mesh samples  "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed."  Do you see that?  A. "Detected".  Q. Thank you. Do you see that?  A. Yes.  Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh?  A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it.  Q. So unlike this study on hernia mesh, for transvaginal mesh you didn't initially sample the specimens to determine if you could detect nerve ingrowth or not?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you see either a clear space or a whole space where you determine that the mesh was or is and can't be seen, right? MR. ORENT: Objection. THE WITNESS: What I see in the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. There's a discussion here under your methods, that the mesh samples  "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed."  Do you see that?  A. "Detected".  Q. Thank you. Do you see that?  A. Yes.  Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh?  A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it.  Q. So unlike this study on hernia mesh, for transvaginal mesh you didn't initially sample the specimens to determine if you could detect nerve ingrowth or not?  MR. ORENT: Objection.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you see either a clear space or a whole space where you determine that the mesh was or is and can't be seen, right?  MR. ORENT: Objection. THE WITNESS: What I see in the microscope, I see cross-sections of the filaments,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. There's a discussion here under your methods, that the mesh samples  "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed."  Do you see that?  A. "Detected".  Q. Thank you. Do you see that?  A. Yes.  Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh?  A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it.  Q. So unlike this study on hernia mesh, for transvaginal mesh you didn't initially sample the specimens to determine if you could detect nerve ingrowth or not?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you see either a clear space or a whole space where you determine that the mesh was or is and can't be seen, right? MR. ORENT: Objection. THE WITNESS: What I see in the

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Page 94 Page 96 1 the mesh filaments. Therefore, anything inside 1 Q. And this same process that you 2 this boundaries, is new tissue which was generated 2 describe here in this study of drawing an imaginary 3 3 line connecting the outermost points of the after mesh was placed. 4 4 adjacent mesh filaments, is the same process by It was an artificial sort of 5 distinction for us to understand during this study, 5 which you determined the shape of the mesh when 6 6 which nerves were new, new innervation or looking at transvaginal specimens, correct? 7 7 A. No, I don't understand your reinnervation. And which nerves could have been 8 question. Shape in nerves -- they are different 8 trapped in the scar which was expanding into normal 9 tissue. 9 issues. 10 10 BY MS. BYARD: Q. Okay. Let me take it then the way 11 Q. To identify when looking -- let me 11 that you've presented it. 12 12 This same process that you describe in start over. 13 When looking at transvaginal mesh 13 the study of drawing an imaginary line connecting 14 14 the outermost points of adjacent mesh filaments, in slides under microscope, you have to draw the same 15 15 imaginary line connecting the outermost points of order to determine whether nerves were there 16 16 the adjacent mesh filaments in order to record beforehand, or whether they grew into the mesh, is 17 whether nerves are ingrown in the mesh, are whether 17 the same method that you applied to your analysis 18 18 of transvaginal mesh specimens in the litigation, they were preexisting, correct? 19 19 A. Yes, I mean this would be a very correct? 20 strict criteria. Because some nerve branches just 20 A. In litigation, I describe nerve 21 outside of the imaginary line can still be new 21 involvement. I mean, they might be ingrown; they 22 ones. But, I mean, anything beyond those lines is 22 might be just outside. 23 new, by definition. 23 As I said, diagnostically, if the nerve 24 But the one I assess, I make a 24 is affected, it could be outside of the imaginary 25 distinction. Especially if I collect data for 25 line. It can be trapped in the scar tissue or Page 95 Page 97 1 1 research product. But for symptoms as a diagnostic around. 2 tool, it doesn't have much significance. 2 I think it is a little artificial to 3 3 Because as I said, I mean, nerves hook on this imaginary line. It was done for the 4 right -- just outside that line, can be affected to 4 research project. As I said, diagnostically, what 5 5 the same degree as -- it might be microns matters is, if there is an innervation in the 6 difference, here or there, so -- but that was 6 tissue, in that tissue. That's important. 7 7 important for this study, to understand it as Q. To determine whether or not a 8 8 diagnostically this doesn't have much significance. nerve had ingrown into mesh, though, when you were 9 9 Q. Do you know, or did your -- I'm looking at transvaginal mesh specimens, you had to 10 sorry, let me start over. 10 draw this imaginary line connecting the outermost 11 11 Did your research here, look at how, points of adjacent mesh filaments? 12 diagnostically, nerves growing outside of mesh or 12 A. If I want to call it ingrown, yes, 13 13 preexisting nerves, compared in terms of clinical it's important. But diagnostically, is it -- if 14 complications to nerves growing within the mesh? 14 only ingrown nerves are important for diagnostic 15 15 A. In this study? purposes, this is not correct. 16 Q. (Nods.) 16 Because ingrown nerves which are inside 17 17 A. In this study, we, as I said, the compartment, they are much deeper. But at the 18 18 establish baseline. same time, if a nerve is just outside, it branches, 19 19 Q. So the answer to my question is, and then supplies nerve endings, small branches in "no, you did not," right? 20 20 the tissue inside. 21 21 MR. ORENT: Objection. Q. Please listen to my question, sir. 22 THE WITNESS: Well, you see that there 22 In order to determine whether nerve was 23 is no specific correlation with clinical 23 ingrown in mesh, when examining transvaginal mesh 24 24 presentation in this specific study. specimens, you had to draw this same imaginary line 25 BY MS. BYARD: 25 that you describe in your study with Bendavid,

	Page 98		Page 100
1	connecting the outermost points of adjacent mesh	1	MR. ORENT: Objection.
2	filaments, didn't you?	2	THE WITNESS: No.
3	MR. ORENT: Objection. Asked and	3	BY MS. BYARD:
4	answered. Moreover, Dr. Iakovlev is entitled to	4	Q. And so you didn't adjust
5	give a full and complete response to the questions	5	calculate an adjustment ratio, and your examination
6	and he will continue to do so and	6	and analysis of transvaginal mesh for litigation,
7	MS. BYARD: Please limit your	7	correct?
8	objections to form, sir.	8	MR. ORENT: Objection.
9	MR. ORENT: Asked and answered.	9	THE WITNESS: Again, we are going from
10	THE WITNESS: As I said, in the	10	research from scientific question to diagnostic
11	description if I say ingrown, I use this imaginary	11	processes.
12	line. But diagnostically, this has not it	12	I don't base my opinion on adjustment
13	doesn't have much significance. Because what I do	13	ratios or on the specifics of what I did in the
14	in diagnostically, I try to estimate or assess if	14	-
15		15	research part. I don't BY MS. BYARD:
	the tissue is innervated. That's what important.  BY MS, BYARD:	16	
16			Q. My only question is whether you
17	Q. But whether you determine that a	17	did it?
18	nerve was ingrown, depends completely on whether it	18	A. I never used it. It was only used
19	lies within the parameters of this imaginary line	19	once for this specific study, for specific
20	that you've drawn?	20	question. It wasn't diagnostic question. It was
21	MR. ORENT: Objection. Asked and	21	more of a mathematical question.
22	answered.	22	Q. I want to turn to page 802 of 1197.
23	THE WITNESS: Ingrown where? Ingrown	23	The last two full sentences before the
24	in the scar, or ingrown inside the mesh?	24	figures read:
25	BY MS. BYARD:	25	"The branches located at the
	Page 99		Page 101
1			
	Q. Ingrown inside the mesh, please.	1	mesh interface tended to have an
2	<ul><li>Q. Ingrown inside the mesh, please.</li><li>A. If it's ingrown inside the mesh</li></ul>	1 2	mesh interface tended to have an orientation parallel to the mesh
		l .	
2	A. If it's ingrown inside the mesh	2	orientation parallel to the mesh
2	A. If it's ingrown inside the mesh and I make a statement	2	orientation parallel to the mesh plane."
2 3 4	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection.	2 3 4	orientation parallel to the mesh plane."  A. That's correct.
2 3 4 5	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond	2 3 4 5	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse
2 3 4 5 6	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not	2 3 4 5 6	orientation parallel to the mesh plane." A. That's correct. Q. "Some branches showed a coarse angled to the mesh plane, and nine
2 3 4 5 6 7	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it	2 3 4 5 6 7	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90
2 3 4 5 6 7 8	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.	2 3 4 5 6 7 8	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of
2 3 4 5 6 7 8 9	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic	2 3 4 5 6 7 8	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure.
2 3 4 5 6 7 8 9	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research.	2 3 4 5 6 7 8 9	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure.  Table 1."
2 3 4 5 6 7 8 9 10	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic process with our research.  Descriptive term can be, if I make a	2 3 4 5 6 7 8 9 10	orientation parallel to the mesh plane."  A. That's correct. Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure.  Table 1." A. That is correct.
2 3 4 5 6 7 8 9 10 11	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic process with our research.  Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that	2 3 4 5 6 7 8 9 10 11 12	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure.  Table 1."  A. That is correct.  Q. What do you mean by, "the branches
2 3 4 5 6 7 8 9 10 11 12 13	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line.	2 3 4 5 6 7 8 9 10 11 12	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an
2 3 4 5 6 7 8 9 10 11 12 13 14	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD:	2 3 4 5 6 7 8 9 10 11 12 13 14	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that were located at the mesh interface were running
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate picture of the rate of nerve ingrowth, correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that were located at the mesh interface were running parallel to the mesh as opposed to through it?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue. I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate picture of the rate of nerve ingrowth, correct? A. Not rate, density.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that were located at the mesh interface were running parallel to the mesh as opposed to through it?  A. Yes, that's how you would orient
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate picture of the rate of nerve ingrowth, correct? A. Not rate, density. Q. Density, thank you.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."  A. That is correct. Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that were located at the mesh interface were running parallel to the mesh as opposed to through it?  A. Yes, that's how you would orient any cable. Just think about cables. There's a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.  I think we are mixing up diagnostic process with our research. Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line. BY MS. BYARD: Q. Thank you. Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate picture of the rate of nerve ingrowth, correct? A. Not rate, density. Q. Density, thank you. With respect to your examination of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	orientation parallel to the mesh plane."  A. That's correct.  Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure.  Table 1."  A. That is correct.  Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?  A. They had orientation parallel to the mesh plane.  Q. So the majority of the nerves that were located at the mesh interface were running parallel to the mesh as opposed to through it?  A. Yes, that's how you would orient any cable. Just think about cables. There's a cable, and then you run it in the corner because

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Page 102 Page 104 1 Nerve branch goes along the plane, and 1 A. No, this is not my testimony. 2 then there are small branches going into the mesh 2 It's higher. And on an average, the last time I 3 3 and they innervate inside tissue. It's logical calculated, it's about six times higher. What is 4 4 biological. an average number of nerves I see, and I'm talking 5 5 Q. Is this same finding -- let me about densities, which was about six times higher. 6 Number of nerves I see, I don't know 6 start over. 7 Were your findings about the 7 now. It's much higher. I mean, it's definitely 8 8 orientation of the branches of nerves located at not one to three, it's about beyond ten or so. 9 9 the mesh interface similar for transvaginal mesh as And then it depends, I mean, what 10 you've described here for hernia mesh? 10 device we are talking about. Sling, slings tend to 11 A. Transvaginal mesh is different 11 have smaller specimens. POP devices, it might be 12 because there are no anatomical planes. In the 12 over a hundred of nerves that I see in one section, 13 hernia, in the anterior abdominal wall, you have 13 it depends. 14 layers which are separated by fascia, serrated 14 Q. So the way you went about arriving 15 15 muscle, so there are anatomical planes. at this number for your valuation of hernia repair, 16 In transvaginal location, there is no 16 was to actually count the number of nerves per 17 anatomical plane. Tissues just merge into each 17 specimen, correct? 18 other. The orientation of nerves is a little bit 18 A. That's correct. 19 19 different, because in the anterior abdominal wall, Q. And you haven't done that counting 20 most of the nerves run parallel to supply further; 20 activity for transvaginal mesh specimens? 21 so the mesh is placed parallel. 21 A. I have not. 22 22 In the transvaginal location, the nerve MR. ORENT: Objection. 23 branches are running to innervate mucosa. And the 23 THE WITNESS: There are reports, 24 mesh is placed perpendicular, so this is completely completed surgical pathology reports with synoptic 25 a different anatomical structure. 25 data, and there is a full count. Page 103 Page 105 1 1 So in transvaginal meshes, they are all Again, it's not what I am basing my 2 over the place, and I did not see that predominance 2 opinion, but this was done more for research 3 of parallel orientation. It's different anatomical 3 purpose later on. 4 4 structure. BY MS. BYARD: 5 5 Q. You write that the number of Q. Okay. So in answer to my 6 nerves ingrown -- and I've switched to page 803. 6 question, you haven't done this type of overall 7 7 On page 803, the first full sentence you write: analysis of counting the nerves, the number of 8 8 "The number of nerves ingrown nerves that you see grown into mesh structure for 9 9 into the mesh structures range from transvaginal mesh, right? 10 10 MR. ORENT: Objection. Asked and one to three per examined portion of 11 a specimen." 11 answered. 12 12 Correct? THE WITNESS: I have done it. When the 13 A. That's correct. 13 complete surgical report is issued, it contains 14 Q. Were your findings in examining 14 these numbers. 15 transvaginal mesh specimens similar to your 15 BY MS. BYARD: 16 findings here on hernia mesh? 16 Q. Whose complete surgical report? 17 17 A. No. Densities are much higher in A. There's some, I think I completed 18 transvaginal meshes. About six times on average 18 it to -- when I sign out a surgical pathology 19 19 than in inguinal hernia. report in St. Michael's system, I include full 20 20 analysis for nerve report -- nerve densities. Q. So when you see the number of 21 nerves ingrown into mesh structures and hernia 21 Q. So there are some cases where 22 repair ranging from one to three per examined 22 you've completed a complete St. Michael's surgical 23 portion of the mesh; the number would be closer to 23 pathology report and others where you haven't, 24 6 to 18 nerves per examined specimen for 24 correct? 25 transvaginal mesh? Is that your testimony? 25 A. For most of this, I didn't have

1	Page 106		Page 108
1	time to complete the surgical pathology reports.	1	question.
2	But you have at least one here, I think	2	A. I've done it.
3	for Ms. Holland.	3	MR. ORENT: Objection.
4	MR. ORENT: Tab 1.	4	THE WITNESS: You asked me if I've done
5	BY MS. BYARD:	5	it for 120. I've done the count for those which
6	Q. I know what you're referring to	6	were completed cases.
7	and we'll look at that tomorrow.	7	I have stacks of cases at different
8	A. Okay.	8	stages of completion. It's work in progress for
9	Q. Take the time you need, I know	9	some of them. But with the cases completed,
10	what you're referring to, though.	10	altogether with a surgical pathology report, there
11	A. So how this is done, when I	11	is count. For each single specimen completed,
12	Q. That's okay, there's no question	12	there is count of nerves and nerve densities.
13	pending.	13	BY MS. BYARD:
14	MR. ORENT: That's the report you're	14	Q. And of the 25-plus cases we will
15	looking for?	15	talk about tomorrow, you have one example of that,
16	THE WITNESS: Yeah, the densities here,	16	right?
17		17	MR. ORENT: Objection. Misstates his
18	right there. BY MS. BYARD:	18	testimony.
19	Q. So my question is focused on your	19	THE WITNESS: Not example. One case is
20	analysis which case is that?	20	completed in that respect.
21	A. This one.	21	BY MS. BYARD:
22	MR. ORENT: Lucy Allen.	22	Q. Okay. And the range of the number
23	•	23	of nerves ingrown into mesh structures for
24	MS. BYARD: Okay.	24	<del>-</del>
25	(Reporter sought clarification).	25	transvaginal mesh in the 120 specimens that are
25	MR. ORENT: Lucy Allen.	25	detailed in your report, doesn't appear in your
	Page 107		Page 109
1	And he's pointing to the line that		
i		1	report, does it?
2	reads, "was it 59 branches?"	2	MR. ORENT: Objection.
2	reads, "was it 59 branches?" BY MS. BYARD:	l .	MR. ORENT: Objection. THE WITNESS: No, I didn't record it.
	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused	2	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific
3	reads, "was it 59 branches?" BY MS. BYARD:	2	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.
3 4	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.	2 3 4	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD:
3 4 5	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the	2 3 4 5	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.
3 4 5 6	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.	2 3 4 5 6	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD:
3 4 5 6	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at	2 3 4 5 6 7 8	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.  BY MS. BYARD:  Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am
3 4 5 6 7 8 9	reads, "was it 59 branches?"  BY MS. BYARD:  Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches	2 3 4 5 6 7 8	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.  BY MS. BYARD:  Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay?
3 4 5 6 7 8 9 10	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?	2 3 4 5 6 7 8 9 10	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD: Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803
3 4 5 6 7 8 9 10 11	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.	2 3 4 5 6 7 8 9 10 11 12	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.  BY MS. BYARD:  Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay?  You conclude this paragraph on page 803 of Exhibit 1197 by saying:
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3 4 5 6 7 8 9 10 11 12 13 14 15 16	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.  BY MS. BYARD:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MR. ORENT: Objection.  THE WITNESS: No, I didn't record it.  Because I'm not basing my opinion for that specific for this specific purpose we are here today.  BY MS. BYARD:  Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay?  You conclude this paragraph on page 803 of Exhibit 1197 by saying:  "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.  BY MS. BYARD: Q. That doesn't appear in your report, does it?  A. Which, which report?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD: Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue." A. That's correct. Q. Here you compared the number of nerves ingrown into pores with the number of nerves
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.  BY MS. BYARD: Q. That doesn't appear in your report, does it?  A. Which, which report? Q. In your report, Exhibit 197?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD: Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue." A. That's correct. Q. Here you compared the number of
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.  BY MS. BYARD: Q. That doesn't appear in your report, does it?  A. Which, which report? Q. In your report, Exhibit 197? A. Which one? I don't understand.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD: Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue." A. That's correct. Q. Here you compared the number of nerves ingrown into pores with the number of nerves
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reads, "was it 59 branches?"  BY MS. BYARD: Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.  You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.  BY MS. BYARD: Q. That doesn't appear in your report, does it?  A. Which, which report? Q. In your report, Exhibit 197? A. Which one? I don't understand. Q. Or 196.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. ORENT: Objection. THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific for this specific purpose we are here today. BY MS. BYARD: Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue." A. That's correct. Q. Here you compared the number of nerves ingrown into pores with the number of nerves that were seen in the examined tissue as a whole?

28 (Pages 106 to 109)

Page 110 Page 112 1 Q. And compared to the number of 1 scientific question, I will complete it. But 2 nerves that were in the examined tissue overall, 2 again, the conclusions in this paper were not based 3 3 the number of nerves that were grown into pores, on this number. This number was provided for was a median of 6.3 percent with a range of 2.17 to 4 readers to understand what is going on. 4 5 5 15.8 percent, correct? BY MS. BYARD: 6 6 Q. Could you tell me, sitting here A. That's correct. 7 Q. Have you performed this same 7 today, what percentage of nerves you would expect 8 8 statistical analysis for the transvaginal mesh to be ingrown compared to not ingrown and present 9 9 specimens? in tissue for transvaginal mesh? 10 A. For those I completed test, I 10 A. At least the same as in hernia. 11 mean, it's somewhere in the spreadsheet. I started 11 As I said, likely several fold higher as well, 12 testing that as well. But it's only when the nerve 12 because of difference in anatomical orientation. 13 count is completed that I can do it. 13 As I said, in transvaginal location, 14 14 Q. So it's not in your report, is it? there are branches that going to innervate mucosa, 15 A. No. It has no diagnostic 15 so they're perpendicular to the mesh. So I'm 16 significance. One nerve is enough. I mean, if you 16 expecting to see much higher percentage. 17 have one nerve in the tooth and it hurts, it's just 17 Q. That's a working hypothesis at 18 one nerve is enough. 18 this point, but not a scientific conclusion arrived 19 MS. BYARD: Object and move to strike 19 at through the same type of statistical analysis --20 after the words, "No, it's not in the report." 20 MR. ORENT: Objection. 21 MR. ORENT: Oppose. 21 BY MS. BYARD: 22 22 BY MS. BYARD: Q. -- right? 23 Q. Do you know how the percentage of 23 A. Yes, this is. But it will be at 24 nerve ingrowth in transvaginal mesh samples within 24 least 6.3 percent. Again, diagnostically, it's 25 mesh structures compares to the number of nerves in irrelevant. For specific patients, for specific Page 111 Page 113 1 1 transvaginal mesh specimens overall? purpose we're here today. 2 MR. ORENT: Objection. 2 Q. And here you have this nerve 3 THE WITNESS: I think I answered that 3 assessment data Table 1 on page 804. 4 generally, density is about six times higher. I 4 A. Yes. 5 5 mean, it depends on how you group those devices. Q. And the transvaginal specimen 6 If you split them into slings versus POP devices, 6 analysis that you have done, did you compare virgin 7 7 but generally several fold higher. tissue and scar tissue with actual samples? 8 8 BY MS. BYARD: A. No --9 9 MR. ORENT: Objection. O. That's true across the tissue 10 10 THE WITNESS: -- I mean I don't specimen, though, correct? 11 11 A. Transvaginal. If we compare understand why you're asking these questions. And 12 12 I didn't complete -- this was different study and transvaginal versus inguinal hernia, that's true. 13 Q. What I am focused on now is the 13 just, I mean, this is -- again, as I said, this is 14 amount of nerves growing into the mesh pores 14 not diagnostically relevant. 15 compared to the amount of nerves overall. And we 15 MS. BYARD: Object and move to strike 16 know from your study that it's around 6.3 percent 16 everything besides, "no." 17 for inguinal hernia repair mesh. 17 MR. ORENT: So are you suggesting by 18 I'm asking if you have a percentage for 18 your repeated motions to strike, that he's not 19 19 me of the percentage rate of nerve ingrowth into entitled to give a full answer? 20 20 compartmentalized pores for transvaginal mesh as MS. BYARD: I don't think I have to 21 compared to the number of tissues overall in the 21 answer your question for the basis of my motion. 22 22 specimens that you've examined? I just -- my questions are simple, and 23 MR. ORENT: Objection. 23 we're going to be here a long time if I can't just 24 THE WITNESS: As I said, that work is 24 get answers to my questions. 25 not completed. It is not done yet. If there is a 25 MR. ORENT: I think that's what he is

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Page 114
                                                                                                     Page 116
 1
      doing. And I think you're going beyond the scope
                                                           1
                                                                      BY MS. BYARD:
 2
      of what he's even intending to offer at trial. So
                                                           2
                                                                       Q. That's not in your report?
 3
                                                           3
                                                                      A. That's for research, the report is
      if we stick to his opinions, we can move fast, too.
 4
                                                           4
                                                                diagnostic. Again, the same issue. We are mixing
             But, Doctor, you can go ahead and keep
                                                           5
 5
      answering your questions as you see fit.
                                                                up unmixable things. Research and diagnostic work.
 6
             BY MS. BYARD:
                                                           б
                                                                       Q. That's not in your report is it,
                                                           7
 7
             Q. So here for this study, you've
                                                                sir?
                                                           8
                                                                      MR. ORENT: Objection.
 8
      used control samples, haven't you?
                                                                      THE WITNESS: There is no statistics of
 9
             A. For this study, yes.
                                                           9
                                                         10
10
             Q. You used the control sample in
                                                                comparison at all, because my reports are
11
      virgin tissue?
                                                         11
                                                                diagnostic reports, and this is research.
                                                         12
12
             MR. ORENT: Objection. Asked and
                                                                      BY MS. BYARD:
13
                                                         13
                                                                       Q. So you agree with me it doesn't
      answered.
                                                         14
14
             THE WITNESS: Yes.
                                                                appear in your report?
15
                                                         15
                                                                      MR. ORENT: Objection. Asked and
             BY MS. BYARD:
16
                                                         16
                                                                answered for the fourth time.
             Q. You used another control sample in
17
      scar tissue, correct?
                                                         17
                                                                      THE WITNESS: There was no research
18
             MR. ORENT: Objection. Asked and
                                                         18
                                                                methodology or -- the reports are not research
19
                                                         19
                                                                project. They are reports.
      answered.
20
             THE WITNESS: Scar tissue was control
                                                         20
                                                                      BY MS. BYARD:
21
                                                         21
                                                                       Q. So the answer to my question is,
      and at the same time, it was a test group depending
22
                                                         22
      on how we compare them.
                                                                no, that control group in virgin tissue is not set
23
             BY MS. BYARD:
                                                         23
                                                                forth or analyzed in your report in the litigation?
24
             Q. In your report on your 120
                                                         24
                                                                      MR. ORENT: Objection.
25
      specimens for transvaginal mesh, you don't have a
                                                         25
                                                                      THE WITNESS: It's not mentioned, but I
                                           Page 115
                                                                                                     Page 117
 1
      control group in virgin tissue?
                                                                know about the mesh tissue, or human body
 2
             A. This is research. This is
                                                           2
                                                                interactions based on this study.
 3
      diagnostic work. We are mixing things which are
                                                           3
                                                                       So in order to produce this report, I
 4
      completely unmixable. I just don't understand why
                                                           4
                                                                used my knowledge, which I gained through my
                                                           5
 5
                                                                training, through this study and other studies, and
      we are doing this.
 6
             Q. Please answer my question.
                                                           6
                                                                then I make conclusions in diagnostic report. I
                                                           7
 7
             MR. ORENT: Objection. Asked and
                                                                could not put everything which I know or which --
 8
                                                           8
                                                                or research studies I've done and the reports.
      answered.
             THE WITNESS: This is research. This
                                                           9
 9
                                                                       BY MS. BYARD:
10
      is diagnostic work. Can you repeat the question so
                                                         10
                                                                       Q. Have you done an analysis of nerve
      I understand what we are talking about, research or
                                                                assessment data on vaginal virgin tissue?
11
                                                         11
12
      diagnosis?
                                                         12
                                                                       MR. ORENT: Objection.
                                                                       THE WITNESS: As I said, it's work in
13
             MS. BYARD: Would you mind reading back
                                                         13
14
      my question, Madam Court Reporter?
                                                         14
                                                                progress. It will be done when I complete.
15
             REPORTER'S NOTE: Whereupon the
                                                         15
                                                                       BY MS. BYARD:
16
      question was read back as follows:
                                                         16
                                                                       Q. To date, it hasn't been completed?
17
                "In your report on your 120
                                                         17
                                                                       MR. ORENT: Objection.
18
             specimens for transvaginal mesh, you
                                                         18
                                                                       THE WITNESS: No.
19
             don't have a control group in virgin
                                                         19
                                                                       BY MS. BYARD:
20
             tissue?"
                                                         20
                                                                       Q. And the same thing is true for
21
             MR. ORENT: Objection.
                                                         21
                                                                vaginal scar tissue, correct?
22
             THE WITNESS: I do. There are samples
                                                         22
                                                                       A. As I said, it was not a question
23
      in St. Michael's Hospital of transvaginal mucosa
                                                         23
                                                                for the reports. The reports describe pathological
24
      excised. So when the study is completed, I intend
                                                         24
                                                                findings which I see, which I know pathological
25
      to examine those as well.
                                                         25
                                                                already.
```

30 (Pages 114 to 117)

```
Page 118
                                                                                                     Page 120
 1
              We're talking about research questions.
                                                           1
                                                                       BY MS. BYARD:
 2
      Sometimes it's question which is not relevant
                                                           2
                                                                       Q. In terms of the number of nerves
                                                           3
 3
      specifically to diagnostic process.
                                                                present in tissue specimens density?
                                                           4
                                                                       A. My expectation is that the scar
 4
              Q. The answer to my question is that,
 5
      no, that analysis has not been completed to date,
                                                           5
                                                                outside of the mesh would have about the same nerve
                                                           б
 6
      right?
                                                                density as an irregular scar from after any
                                                           7
 7
                                                                procedure.
              MR. ORENT: Objection.
              THE WITNESS: The answer is, yes, I
                                                           8
 8
                                                                       In regards to innervation inside the
                                                           9
 9
      have not completed the analysis of transvaginal
                                                                mesh, it will be somewhat lower than innervation
                                                          10
10
      meshes for research purpose.
                                                                outside. But again, it's not clinically relevant
11
              BY MS. BYARD:
                                                          11
                                                                because the fact that it can ingrow, that's the
12
                                                          12
              Q. And I'm focusing on an analysis of
                                                                most important clinical question.
13
      vaginal scar tissue.
                                                          13
                                                                       Q. And again, whether or not the
                                                          14
14
              MR. ORENT: Is there a question there?
                                                                number of nerves that ingrow at the mesh is lower,
15
                                                          15
                                                                or whether it's statistically significantly lower,
              BY MS. BYARD:
16
                                                          16
                                                                is an open hypothesis at this point, true?
              Q. Same question for vaginal scar
17
                                                          17
                                                                       MR. ORENT: Objection.
      tissue.
18
              MR. ORENT: Objection to form.
                                                          18
                                                                       THE WITNESS: I don't understand why we
              THE WITNESS: That, that's correct.
19
                                                          19
                                                                are asking this. I mean, diagnostic process is --
20
              BY MS. BYARD:
                                                          20
                                                                       BY MS. BYARD:
21
                                                          21
                                                                       Q. Sir, you don't need to agree with
              Q. You write that you:
                                                          22
22
                 "Detected no indication that
                                                                my questions or why I'm asking them --
                                                                       MR. ORENT: Excuse me. He's answer --
23
              the scar around and within the mesh
                                                          23
24
              has significantly lower innervation
                                                          24
                                                                       BY MS. BYARD:
25
              than an ordinary scar." Correct?
                                                          25
                                                                       Q. -- you just need to answer them.
                                                                                                     Page 121
                                            Page 119
                                                           1
 1
             A. That's correct.
                                                                       MR. ORENT: Counsel, he's entitled to
 2
             Q. Are those same findings true for
                                                           2
                                                                finish. The way this process works is, you ask a
 3
                                                           3
                                                                question, he answers. You don't cut him off midway
      transvaginal mesh?
 4
             A. As I said, I mean, we -- to answer
                                                           4
                                                                through his answer.
                                                           5
 5
      these questions which are not relevant to
                                                                       He's entitled to finish his answer,
 6
      diagnostic process, you would have to compare
                                                           6
                                                                then you can say whatever you want to say.
                                                           7
 7
      vaginal scar and the scar in around meshes.
                                                                       Doctor?
                                                           8
 8
              Q. And that work has not been
                                                                       MS. BYARD: If you wouldn't mind,
                                                           9
                                                                Counsel, I think it would be productive for you to
 9
      completed to date, correct?
10
                                                          10
                                                                provide some guidance to the witness about not
             A. It has not been completed.
                                                          11
                                                                disputing why I'm asking a question.
11
              Q. Based on your observations to
12
      date, do you expect that the innervation within a
                                                          12
                                                                       MR. ORENT: Well, if he doesn't
                                                          13
13
      mesh scar conglomerate is the same as within
                                                                understand, I think he's trying to understand where
14
                                                          14
                                                                this fits and so that he can answer the question.
      vaginal scarring?
15
             MR. ORENT: Can you repeat that or read
                                                          15
                                                                I don't think he's trying to be difficult.
16
      that one back?
                                                          16
                                                                       But, Doctor, if you could answer.
                                                          17
17
             REPORTER'S NOTE: Whereupon, the
                                                                       THE WITNESS: So my response is because
18
                                                          18
                                                                as far as I understand, we're talking about the
      pending question was read back as follows:
                                                          19
19
                 "Based on your observations to
                                                                conclusions I derived based on my training,
                                                          20
                                                                knowledge, experience and the research included in
20
             date, do you expect that the
                                                          21
21
              innervation within a mesh scare
                                                                this one.
22
                                                          22
                                                                       But it appears that you equate research
             conglomerate is the same within
23
              vaginal scarring?"
                                                          23
                                                                with the diagnostic process. Whatever I have done
                                                          24
                                                                in this study was in my head before I looked at
24
              MS. BYARD: Let me add to that.
25
                                                          25
                                                                these specimens.
```

Page 122 Page 124 1 BY MS. BYARD: 1 nerves." Correct? 2 Q. And I'm trying to understand what 2 A. That's correct. That's a 3 you've done on hernia repair and what you've done 3 statement. It has no diagnostic conclusion or 4 on transvaginal mesh, okay? 4 anything else. 5 5 A. Okay. Q. Why did you include that language? 6 6 A. As I said, it's a description of Q. And at this point, whether or not 7 the rate of nerve growth within transvaginal mesh 7 what we see, just for readers to understand what's 8 is less than the rate of nerve growth in the scar going on under the microscope. 8 9 surrounding the mesh is an open hypothesis, 9 Q. There are clinicians who 10 10 correct? contributed to this paper, right? 11 MR. ORENT: Objection. 11 A. Yes. 12 THE WITNESS: I can tell you that I 12 Q. Is it possible that to Dr. Bendavid 13 have some initial data, initial observations, but 13 or to Dr. Koch, that whether these were similar in 14 it's not completed. Statistics is not completed 14 size to ilioinguinal or iliohypogastric nerves had 15 15 yet. some clinical bearing? 16 16 MR. ORENT: Objection. Calls for BY MS. BYARD: 17 Q. Okay. Thank you, sir. 17 speculation. 18 Just to paraphrase, your findings with 18 THE WITNESS: Had no clinical bearing. 19 respect to hernia repair was that both scar tissue 19 BY MS. BYARD: 20 and scar tissue with mesh have a higher number of 20 Q. Did you write this sentence or did 21 nerves than virgin tissue, but that the difference 21 they? 22 between the two groups was not statistically 22 MR. ORENT: Objection. THE WITNESS: Oh, their manuscript was 23 significant? That's correct? 23 24 A. (Witness nods.) 24 edited, rewritten several times, several people 25 Q. Now, if you look at the last 25 contributed. Page 123 Page 125 1 paragraph of the result section, which is just 1 I certainly contributed to each 2 before "discussion," you measured the nerves that 2 sentence in one way or another. And I measured. 3 you saw, right? And by that I mean, you measured 3 Nobody else could measure them. 4 their size? 4 BY MS. BYARD: 5 5 A. Diameter, yes. Q. Are you the one who supplied the 6 Q. For your evaluation of 6 information about how the nerve sizes and diameter 7 7 transvaginal mesh specimens, you didn't measure the compared to the size of known nerves in this diameter of the nerves that you detected, did you? 8 8 particular anatomy? A. This is comparison of microscopic. 9 A. No. 9 10 10 So I contributed by microscopic what I see, and Q. Part of what you were doing here in your study with Dr. Bendavid, was trying to 11 clinicians contributed to what they can see with 11 12 correlate the size of the diameter of the nerves 12 bare eyes without the microscope. 13 13 that you found to whether they were similar, So the comparison is, roughly, for 14 dissimilar to inguinal or iliohypogastric nerves, 14 surgeons to understand that the nerves we are 15 correct? 15 talking about can be as big as those they can see 16 A. No. 16 by naked eye, but they can be much smaller that 17 17 Q. Tell me what you were trying to do they cannot see them. Therefore, they cannot avoid by measuring the diameter of the nerves then? 18 18 19 19 A. What I've just described, so the So basically it leads to readers to 20 readers would understand what I'm talking about. 20 understand that it's unavoidable to damage nerves 21 Had no diagnostic significance. 21 because they are so small that surgeons cannot see 22 Q. Well, you write: 22 them. 23 "At 0.9 millimeters, the size 23 Q. And it was important for the 24 24 surgeons to talk about the type of nerves that is not too dissimilar from that of 25 the ilioinguinal or iliohypogastric 25 these were similar in size to, correct?

32 (Pages 122 to 125)

	Page 126		Page 128
1	MR. ORENT: Objection.	1	" for a better understanding
2	THE WITNESS: I don't understand the	2	and application of anatomy, which
3	question. What do you mean, "type of nerves"?	3	easily transferred to tension free
4	BY MS. BYARD:	4	
5	Q. Well, it mentions specifically	5	and laparoscopic repairs." Right?  A. That's correct.
6	inguinal and iliohypogastric nerves, doesn't it?	6	
7	A. It's not a type of nerve. It's	7	Q. He writes:
8	* *	1	"Today's leitmotif in hernia
9	just a name of a larger branch.	8	surgery, to accompany the newer
	Q. Here, that name of those branches	9	techniques, has been the extensive
10	was important to specify?	10	use of prosthetic materials."
11	A. No.	11	A. That's correct. That's epidemics
12	Q. It was completely superfluous?	12	now.
13	MR. ORENT: Objection. Argumentative.	13	Q. He used he says:
14	THE WITNESS: This is something which	14	"The philosophy of tension free
15	surgeons have readily are familiar with. It's a	15	repair which was made possible by
16	comparison, it's like a sliding scale, from 1 to	16	the advent of synthetic materials
17	10. So everybody within the span would know what	17	was born in Marseille, France,
18	we're talking about.	18	fathered by Don Aqauviva in 1944,
19	BY MS. BYARD:	19	who used sagittate nylon sheets as
20	Q. You're not a pain specialist,	20	an onlay over a defect which itself
21	right?	21	was left intact."
22	A. What do you mean "pain	22	Did I read that correctly?
23	specialist"?	23	A. Yeah, you read it correctly.
24	Q. You don't treat and manage pelvic	24	Q. He says:
25	pain, do you?	25	"The theme was re-visited by
	Page 127		Page 129
1	A. That's correct.	1	Henri Fruchaud in 1956, who designed
2	Q. And you're not a neurologist?	2	an operation also using nylon mesh
3	A. No, I am not a neurologist. You	3	in a manner which was antedated and
4	know what I am, I am pathologist.	4	precisely anticipated Francis Usher."
5	Q. And you're not a specialist in		
		5	
6		5 6	Did I read that correctly?
	sexual health, correct?	6	Did I read that correctly?  A. Yes, it appears you read it
7	sexual health, correct?  A. I just answered, I'm a	6 7	Did I read that correctly?  A. Yes, it appears you read it correctly.
7 8	sexual health, correct?  A. I just answered, I'm a pathologist.	6 7 8	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the
7 8 9	sexual health, correct?  A. I just answered, I'm a pathologist.  Q. Let's look at the discussion,	6 7 8 9	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene
7 8 9 10	sexual health, correct?  A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:	6 7 8 9	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's
7 8 9 10 11	sexual health, correct?  A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber	6 7 8 9 10 11	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."
7 8 9 10 11 12	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the	6 7 8 9 10 11 12	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?
7 8 9 10 11 12 13	A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that:     "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."	6 7 8 9 10 11 12	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.
7 8 9 10 11 12 13	A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's	6 7 8 9 10 11 12 13 14	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in
7 8 9 10 11 12 13 14	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.	6 7 8 9 10 11 12 13 14	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:
7 8 9 10 11 12 13 14 15	A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that:     "Indolent years of barber     surgeons and anatomists and the     beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's contribution in this part. Q. I like his writing style.	6 7 8 9 10 11 12 13 14 15	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical
7 8 9 10 11 12 13 14 15 16	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:     "Indolent years of barber     surgeons and anatomists and the     beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's contribution in this part. Q. I like his writing style. A. English is not my first language,	6 7 8 9 10 11 12 13 14 15 16 17	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles
7 8 9 10 11 12 13 14 15 16 17	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me.	6 7 8 9 10 11 12 13 14 15 16 17	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been
7 8 9 10 11 12 13 14 15 16 17 18	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me. Q. He writes:	6 7 8 9 10 11 12 13 14 15 16 17 18	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years,
7 8 9 10 11 12 13 14 15 16 17 18	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me. Q. He writes:  "A mini-revival took place with	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me.  Q. He writes:  "A mini-revival took place with the rediscovery of"	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end."
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me.  Q. He writes:  "A mini-revival took place with the rediscovery of" And then he names some researchers and	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end."  Did I read that correctly?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me.  Q. He writes:  "A mini-revival took place with the rediscovery of" And then he names some researchers and surgeons, right?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end."  Did I read that correctly?  A. That's correct.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I just answered, I'm a pathologist.  Q. Let's look at the discussion, please. You describe here that:  "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."  A. Yes, that was mostly Dr. Bendavid's contribution in this part.  Q. I like his writing style. A. English is not my first language, so he writes better than me.  Q. He writes:  "A mini-revival took place with the rediscovery of" And then he names some researchers and	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Did I read that correctly?  A. Yes, it appears you read it correctly.  Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."  Did I read that correctly?  A. That's correct.  Q. And then it continues that in this next full paragraph:  "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end."  Did I read that correctly?

33 (Pages 126 to 129)

	Page 130		Page 132
1	A. Yes.	1	effect on tissue components."
2	Q. And a synthetic polymer discovered	2	That's what's written here in your
3	by J. Paul Hogan and Robert Banks of the Phillips	3	article, right?
4	Petroleum Company; do you see that?	4	A. That's correct.
5	A. I lost you. Yes, I do see that.	5	Q. In this sentence you don't write
6	Q. And it says:	6	that "tissue forces and chemical environment affect
7	"This discovery was made	7	the mesh, which in turn has an effect on tissue
8	possible, thanks to the pioneering	8	components," do you?
9	work and olefin chemistry by two	9	A. I have to see the sentence.
10	Nobel Prize laureates 1963, Giulio	10	MR. ORENT: Where is the sentence
11	Natta and Karl Ziegler."	11	you're looking at, at this point?
12	Do you see that?	12	MS. BYARD: It's the first sentence
13	MR. ORENT: Objection.	13	preceding the discussion of Figure A and Figure B.
14	THE WITNESS: That's correct.	14	THE WITNESS: Oh, this is like a
15	BY MS. BYARD:	15	feedback, this is a description. See, first is
16	Q. And then it goes on to describe	16	description that mesh affects, and then there is
17	there being an "unexpected and unpredicted	17	effect. And then there is a tissue which is
18	prominence of pain" being the most common	18	affecting mesh, and but mesh can react back, so
19	complication seen in mesh groin hernia repairs	19	it's a complex sort of mechanism, which he has not
20	today, doesn't it?	20	studied yet.
21	A. That's correct.	21	BY MS. BYARD:
22	Q. There's a discussion then about	22	Q. And the stage that you're at here
23	the industry development of lighter mesh, meshes	23	with hernia mesh, is understanding the tissue
24	with larger pores. Do you see that?	24	response to mesh, right?
25	A. Yes.	25	MR. ORENT: Objection.
	Page 131		Page 133
1	Q. And it essentially then describes	1	THE WITNESS: It's hard to actually
2	this, this tradeoff in terms of collagen versus	2	differentiate what is mesh response to tissue, or
3	scar tissue ingrowth?	3	tissue response to mesh, or what is mesh effect on
4	A. You would have to read the	4	the tissue, or what is tissue reaction to the mesh.
5	sentence to me.	5	I mean, it's interaction between mesh and tissue.
6	Q. Sure. I just, I would hope to	6	But the intricate details of how this
7	summarize. Essentially here, and correct me if I	7	feeds back and catalyzes the process, I have not
8	don't get this accurately, but essentially here you	8	studied. Molecular mechanisms.
9	go on then to describe there being tradeoffs	9	BY MS. BYARD:
10	between wider pore lighter, larger pore meshes	10	Q. And the same is true for
11	and smaller pore heavier weight meshes, correct?	11	transvaginal mesh, true?
12	A CONTRACT OF CONT	12	MD ODENIE OLI II
	MR. ORENT: Objection.	l .	MR. ORENT: Objection.
13	MR. ORENT: Objection. THE WITNESS: Yeah, we discussed that	13	THE WITNESS: That's correct. We can
13 14	THE WITNESS: Yeah, we discussed that topic.	13 14	THE WITNESS: That's correct. We can see the changes, what is the end result. But how
13 14 15	THE WITNESS: Yeah, we discussed that topic. BY MS. BYARD:	13 14 15	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules,
13 14 15 16	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says:	13 14 15 16	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.
13 14 15 16 17	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex	13 14 15 16 17	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD:
13 14 15 16 17 18	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and	13 14 15 16 17 18	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please.
13 14 15 16 17 18	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of	13 14 15 16 17 18 19	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes.
13 14 15 16 17 18 19 20	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a	13 14 15 16 17 18 19 20	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes. Q. There is a discussion of you all
13 14 15 16 17 18 19 20 21	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a compartmentalized living tissue."	13 14 15 16 17 18 19 20 21	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes. Q. There is a discussion of you all setting up a mesh retrieval industry; do you see
13 14 15 16 17 18 19 20 21 22	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a compartmentalized living tissue." A. That's correct.	13 14 15 16 17 18 19 20 21 22	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes. Q. There is a discussion of you all setting up a mesh retrieval industry; do you see that?
13 14 15 16 17 18 19 20 21 22 23	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a compartmentalized living tissue." A. That's correct. Q. "Additionally, tissue forces	13 14 15 16 17 18 19 20 21 22 23	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes. Q. There is a discussion of you all setting up a mesh retrieval industry; do you see that? A. Yes.
13 14 15 16 17 18 19 20 21 22	THE WITNESS: Yeah, we discussed that topic.  BY MS. BYARD: Q. Sure. And then it says: "To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a compartmentalized living tissue." A. That's correct.	13 14 15 16 17 18 19 20 21 22	THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.  BY MS. BYARD: Q. If you turn to page 808, please. A. Yes. Q. There is a discussion of you all setting up a mesh retrieval industry; do you see that?

34 (Pages 130 to 133)

Page 134 Page 136 1 the registry? 1 after I examine the specimens, then they are all 2 A. Not exactly. Not how 2 put in all table, and then I can see the 3 contributions are made. Dr. Bendavid through his 3 difference. But final statistical analysis is done 4 4 contacts with colleagues, I mean, we started by Dr. Lou, she does statistical tests. 5 5 acquiring meshes just to build a library of Q. So she's inputting the reasons for 6 specimens and examine them. 6 the excision, the clinical presentation, severity 7 Q. And then it says: 7 of the pain, she's inputting that with your 8 8 "The next step will be the histological findings? 9 correlation of histology/pathology 9 MR. ORENT: Objection. 10 10 to the clinical presentation and THE WITNESS: No. I'm receiving the 11 severity of pain." 11 specimens, I'm receiving initial information with 12 A. Yes, that's correct. 12 the specimens. 13 Q. What will your role be in this 13 BY MS. BYARD: 14 14 registry as far as you understand it? O. What initial information? A. Not will be, I'm collecting 15 15 A. Reason for excision. I'm 16 16 specimens, I'm examining them. collecting age, gender, heterology, type of hernia, 17 Q. Is your job to do the correlation 17 is it ventral, is it molecular, is it inguinal, I'm of the histology pathology to the clinical collecting all this clinical information with the 18 18 19 19 presentation and severity of pain? specimen. It comes with specimens. 20 A. Yes. I mean, I examine these 20 Q. You conclude this paragraph by 21 specimens, There is history in them. Statistician 21 writing: 22 22 is involved, so she's Dr. Lou is doing final "This is the duty of our 23 statistical analysis. So statistical tests are 23 profession. It is an oath" -- I'm 24 applied by her. I do some statistics as well on 24 sorry. I didn't start soon enough. 25 25 Let me strike all that. the go and... Page 135 Page 137 1 1 Q. Who's the one evaluating the You write: 2 clinical presentation severity of pain for this 2 "While knowledge comes, let us 3 3 registry, though? translate it into wise application 4 A. Mostly treating clinicians, so 4 for which it was meant. This is the 5 5 they provide -- I mean, at this stage what we duty of our profession, it is an 6 manage to do is separate specimens according to 6 oath which we must honor proudly, 7 reason for excision. 7 disconnected from any notions of 8 8 So if pain is severe enough to cause personal or commercial conflicts of 9 9 excision without any other factors, or if pain was interest." contributing factor as a reason for excision, 10 10 Do you agree with those statements? THE WITNESS: Yes, I do. 11 assuming there is a combination of pain and hernia 11 12 reoccurrence. Or, when the pain either didn't 12 BY MS. BYARD: 13 exist, or pain was low enough not to trigger 13 Q. Here in the conclusion, and we had 14 incision, but mesh was either excised or sampled 14 started to talk about this in the abstract, and so 15 during revision of hernia reoccurrence. So that's 15 I wanted to return to it because you had pointed me 16 where we ended up. I mean, so severity of pain 16 that further on in the paper there would be 17 17 became assessed as a reason for excision. discussion of it. So let's look at that. 18 O. Okay. And that's done by the 18 You write in the conclusion: 19 19 treating physician, correct? "It is felt that the mechanism 20 20 A. Yes. of pain associated with the use of 21 O. And then the correlation between 21 mesh may similarly be due to micro 22 22 the pathology, what you find under microscopic entrapment and micro compartment 23 examination, and this clinical presentation, 23 types of syndromes through new nerve 24 severity of pain, who does that job? 24 and vessel ingrowth within the mesh 25 A. Initially, I see it. I mean, 25 pores and other confining spaces

35 (Pages 134 to 137)

9 referring me back to when we were talking about the 10 abstract? 11 A. Yes. 12 Q. Again, you say that: 13 "It is felt that the mechanism 14 of pain associated with the use of 15 mesh may be due to micro entrapment 16 and micro compartment." Right? 17 A. It says "similarly." 18 Q. So the analogy that you're making 19 A. So the mechanism is similarly. 20 Not that it's due or not due. The "may" implies a similarity. 21 Setween what and what? 22 Q. Between what and what? 23 A. Yes. 24 Q. Between what and what? 25 A. Between compartment syndromes we 20 Tight? 21 A. Yes. 22 P. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities lead to clinical complicat of pain? 24 A. Yes. Details of those mechanisms mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization? 21 THE WITNESS: What do you mean, step behind or in front? 22 BY MS. BYARD: 23 Q. Well, this study, this statistical	2 3 4 5 6 7 8	Page 138		Page 140
thrombi scarring, distortion, migration and traction."  THE WITNESS: That is correct.  BY MS. BYARD: Q. Do you see that? A. That's correct.  Q. And is that what you were referring me back to when we were talking about the abstract?  A. Yes.  Q. Again, you say that: TI is felt that the mechanism of pain associated with the use of and micro compartment." Right?  A. It says "similarly.  Q. So the analogy that you're making. A. So the mechanism is similarly.  Not that it's due or not due. The "may" implies a similarity.  Q. Between what and what? A. Between compartment syndromes we we just discovered.  Page 139  The balance of them, the details and everything else, again, is not studied, it needs be further studied. But the findings, the abcurrent syndromes we pertything else, again, is not studied, it needs be further studied. But the findings, the abcurrent syndisms, the abcurrent syndisms, the abcurrent syndromes we purchangent and everything else, again, is not studied, it needs be further studied. But the findings, the abcurrent syndisms, to solve further studied. But the findings, the abcurrent syndisms visibile, it's there. It's 100 percent there.  Q. So the "you have observed and established tissue abnormalities with hernia merght?  A. Yes.  Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities lead to clinical complicat of pain?  A. Yes. Details of those mechanisms of pain?  A. Yes. Details of hose mechanisms mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization?  MR. ORENT: Objection.  THE WITNESS: What do you mean, step behind or in front?  A. Yes.  BY MS. BYARD:  A. Yes.  BY MS. BYARD:  A. Between compartment syndromes we is further studied. But the findings, the abcurrents wishinch left.  A. Yes.  Q. And with respect to transvaginal mesh, you're one step behind or in front?  A. THE WITNESS: Are you asking in resort of my opinions, or in respect of research and	3 4 5 6 7 8	with the concomitant edema, anoxia,	1	findings are there.
migration and traction."  THE WITNESS: That is correct.  BY MS. BYARD:  Q. Do you see that?  A. That's correct.  Q. And is that what you were referring me back to when we were talking about the abstract?  A. Yes.  Q. Again, you say that:  "It is felt that the mechanism of pain is weight discovered.  A. It says "similarly."  A. So the enchanism is similarly.  D. So the analogy that you're making A. So the mechanism is similarly.  Q. Between what and what?  A. Yes.  Q. Between what and what?  A. Between compartment syndromes we year talking of pain is understood for compartment syndromes that are already know, and these new compartment syndromes that are already established?  "THE WITNESS: That is correct.  4 be further studied. But the findings, the abonomality is visible, it's there. It's abonormality is visible.	4 5 6 7 8		2	
THE WITNESS: That is correct.  BY MS. BY ARD:  Q. Do you see that?  A. That's correct.  Q. And is that what you were  referring me back to when we were talking about the abstract?  A. Yes.  Q. Again, you say that:  Tis felt that the mechanism  of pain associated with the use of  mesh may be due to micro entrapment  for mesh may be due to micro entrapment  A. It says "similarly."  A. So the mechanism is similarly.  Not that it's due or not due. The "may" implies a similarity.  Q. Between what and what?  Q. Between what and what?  A. Between compartment syndromes we perferring me back to when we were talking about the abstract?  A. Yes.  Q. So the you have observed and established itssue abnormalities with hernia meright?  A. Yes.  Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities lead to clinical complicate of pain?  A. Yes. Details of those mechanisms mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization?  MR. ORENT: Objection.  THE WITNESS: That is abnormality is visibile, it's there. It's 100 percent there.  Q. So the you have observed and established is bunched issue abnormalities with hernia meright?  A. Yes.  Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities with hernia meright?  A. Yes.  Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities with hernia meright?  A. Yes.  Q. And with respect to transvaginal mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization?  MR. ORENT: Objection.  THE WITNESS: That is abnormalities with hernia meright?  A. Yes.  A. Yes.  Details of hose mechanism of pain is well and with respect of research and played the mechanism of pain is an division developed to clinical complication.  THE WITNESS: That is abnormalities with hernia me	5 6 7 8		3	
5 BY MS. BY ARD: 6 Q. Do you see that? 7 A. That's correct. 8 Q. And is that what you were 9 referring me back to when we were talking about the 10 abstract? 11 A. Yes. 12 Q. Again, you say that: 13 "It is felt that the mechanism 14 of pain associated with the use of 15 mesh may be due to micro entrapment 16 and micro compartment." Right? 17 A. It says "similarly." 18 Q. So the analogy that you're making 19 A. So the mechanism is similarly. 19 A. So the mechanism is similarly. 20 Not that it's due or not due. The "may" implies a similarity. 21 Q. Between what and what? 22 A. Yes. 23 A. Yes. 24 Q. Between what and what? 25 A. Between compartment syndromes we 26 we just discovered. 3 Q. So the mechanism of pain is 4 understood for compartment syndromes that are 4 already established? 5 abnormality is visibile, it's there. It's 100 percent there. Q. So the you have observed and established tissue abnormalities with hernia m right? A. Yes. Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities lead to clinical complicat of pain? A. Yes. Q. And with respect to transvaginal mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization? A. Yes. Details of those mechanisms mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization?  MR. ORENT: Objection.  Page 139  1 already know, and these new compartment syndromes we is yet to be done. That statistical analysi is yet to be done for transvaginal mesh?  MR. ORENT: Objection.  THE WITNESS: Are you asking in res of my opinions, or in respect of research and pl	6 7 8			• •
6 Q. Do you see that? 7 A. That's correct. 8 Q. And is that what you were 9 referring me back to when we were talking about the 10 abstract? 11 A. Yes. 12 Q. Again, you say that: 13 "It is felt that the mechanism 14 of pain associated with the use of 15 mesh may be due to micro entrapment 16 and micro compartment." Right? 17 A. It says "similarly." 18 Q. So the analogy that you're making 19 A. So the mechanism is similarly. 20 Not that it's due or not due. The "may" implies a similarity. 21 g. Between what and what? 22 Q. Between what and what? 23 A. Yes. 24 Q. Between what and what? 25 A. Between compartment syndromes we 2 we just discovered. 3 Q. So the mechanism of pain is 4 understood for compartment syndromes that are 5 already established?  6 100 percent there. 7 Q. So the you have observed and established tissue abnormalities with hernia m right? A. Yes. Q. The step that hasn't been done yet is understanding the mechanism by which tho tissue abnormalities lead to clinical complicat of pain? A. Yes. Q. And with respect to transvaginal mesh, you're one step behind the study in that haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization? MR. ORENT: Objection. THE WITNESS: What do you mean, step behind or in front? Page 139  1 already know, and these new compartment syndromes we just discovered. 3 Q. So the mechanism of pain is understood for compartment syndromes that are already established? 5 of my opinions, or in respect of research and pl	7 8		5	_
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5 already established? 5 of my opinions, or in respect of research and pl		•		
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	_	•		
7 Q. And the mechanism of pain 7 BY MS. BYARD:				
8 associated with mesh may be similar for compartment 8 Q. I'm talking about the body of		· ·		
	- 4555514	•		scientific knowledge that's available. This was a
10 A. Yeah. Mechanisms may not be 10 contribution to the understanding of the tissue	9 syndroi			
11 exactly the same, but may be similar. Likely to be 11 response to		•		
12 similar. 12 A. Yes, I understand that.	10			=
13 Q. Because at this point in the study 13 Q to hernia repair?	10 11 exactly			
14 of hernia repair, those mechanisms of pain are not 14 A. Are you asking if this analysis	10 11 exactly 12 similar			
15 established yet? 15 was done to derive to the conclusions of this	10 11 exactly 12 similar	· · · · · · · · · · · · · · · · · · ·		
16 MR. ORENT: Objection. 16 report, or are we talking just hypotheticals	10	•		
17 BY MS. BYARD: 17 scientific questions.	10	MR. OREN I: Objection.		
	10 11 exactly 12 similar 13 14 of hern 15 establis			MR. ORENT: Perhaps you can rephrase
19 A. Details of the mechanisms. So 19 the question.	10 11 exactly 12 similar. 13 14 of hern 15 establis 16 17	BY MS. BYARD:		
when we observe the changes in the mesh, we clearly 20 BY MS. BYARD:	10 11 exactly 12 similar. 13 14 of hern 15 establis 16 17 18	BY MS. BYARD: Q. Right?		-
21 saw that the scar tissue within the mesh is not 21 Q. Okay. Let me try and do that.	10 11 exactly 12 similar. 13 14 of hern 15 establis 16 17 18 19	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So		
22 normal scar tissue. 22 And I only am trying to say that with	10 11 exactly 12 similar 13 14 of hern 15 establis 16 17 18 19 20 when w	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So n we observe the changes in the mesh, we clearly		
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innervated, because we saw nerve ingrowth, and we 24 identified abnormalities in the tissue, in mesh?	10 11 exactly 12 similar. 13 14 of hern 15 establis 16 17 18 19 20 when w 21 saw tha 22 normal	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So n we observe the changes in the mesh, we clearly that the scar tissue within the mesh is not nal scar tissue.	22	And I only am trying to say that with
25 saw that it's not regular scar tissue. So the 25 A. Yes. And this exactly the same in	10 11 exactly 12 similar. 13 14 of hern 15 establis 16 17 18 19 20 when w 21 saw tha 22 normal 23	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So n we observe the changes in the mesh, we clearly that the scar tissue within the mesh is not nal scar tissue. So we knew that this tissue is	22 23	And I only am trying to say that with respect to hernia repair, you understand you've

36 (Pages 138 to 141)

	Page 142		Page 144
1	transvaginal meshes.	1	Exhibit 1196?
2	Q. You've identified tissue abnormalities?	2	A. It's not scientific rigor or
3	A. Even more. I found more in	3	scientific work. This is diagnostic work; this is
4	transvaginal meshes than in what is the hernia	4	scientific work. This is diagnostic work, this is
5	meshes.	5	diagnostic. When I see abnormal, I state. Here is
6	Q. Okay.	6	a specific question.
7	A. So in this respect, this part is	7	I mean, you're just trying to mix
8	step ahead from this.	8	things which are not not the same.
9	*	9	Q. But you've made conclusions in
10	Q. Well, in terms of the degree of	10	your report on transvaginal mesh that are broader
11	abnormalities, you're saying?	11	•
	MR. ORENT: Objection.		than the conclusions that you've reached in this
12	THE WITNESS: Yes.	12	study?
13	BY MS. BYARD:	13	A. Yes.
14	Q. Okay.	14	MR. ORENT: Objection.
15	A. There are way more findings in	15	BY MS. BYARD:
16	transvaginal meshes than in hernia meshes. This	16	Q. Right?
17	study was specifically focused on nerve ingrowth.	17	MR. ORENT: Point out a particular
18	What we found there, abnormality in the scar tissue	18	question if you have one.
19	was observation only, sort of, on the way we did	19	THE WITNESS: This part okay.
20	the study.	20	BY MS. BYARD:
21	This was done later, and there are more	21	Q. Go ahead.
22	findings, more abnormalities in transvaginal	22	A. No.
23	meshes.	23	MR. ORENT: Wait for a proper question.
24	Q. You've gotten to the level,	24	MS. BYARD: Are you instructing him not
25	though, of doing a statistical analysis to quantify	25	to answer that question?
	Page 143		Page 145
1		1	
1 2	the tissue abnormalities for hernia mesh?	1	MR. ORENT: No. I think there's no
	the tissue abnormalities for hernia mesh? A. Yes.	2	MR. ORENT: No. I think there's no question pending that's intelligible.
2 3	the tissue abnormalities for hernia mesh? A. Yes. Q. And you haven't reached that stage	2 3	MR. ORENT: No. I think there's no question pending that's intelligible.  All you said is, "there are some
2 3 4	the tissue abnormalities for hernia mesh? A. Yes. Q. And you haven't reached that stage yet for transvaginal mesh?	2	MR. ORENT: No. I think there's no question pending that's intelligible.  All you said is, "there are some opinions in here that are broader than those." But
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37 (Pages 142 to 145)

Page 146 Page 148 1 symptom, had to be excised. How this all happened 1 innervation of the tissue, the tissue would not 2 in small details, up to very small molecules of how 2 sense any pain. So this is, this is predictable. 3 3 they interact, is not known. If we have inflammation, we know that But we know the effect, and we know the 4 4 there will be lower threshold for pain. This has 5 pathological findings behind it. But the details 5 been studied extensively in other areas of 6 б of this connection, these small sort of details are inflammation. Inflammation is always associated 7 7 with lower threshold of pain. What doesn't hurt in not clear. 8 8 normal tissue, may hurt in inflamed tissue. Some of it is, as mentioned, are 9 9 similar to more study there is, like toothache I So inflammation is high enough, it will 10 said, or heart attack. But again, this is in 10 cause pain on its own. Inflammation itself will be 11 11 enough to cause pain, but it may not be enough, and pieces. 12 BY MS. BYARD: 12 then it will need the extra stimulus such as edema. 13 Q. So, for instance, you could have a 13 This is very complex interaction. 14 14 nerve that was grown into scar tissue, that doesn't BY MS. BYARD: 15 15 cause so much pain that the scar tissue has to be Q. And so -- but those specific 16 16 excised, right? mechanisms of how this relationship between nerve 17 MR. ORENT: Objection. 17 ingrowth or vascular ingrowth, scar tissue, 18 THE WITNESS: This can happen. I mean, 18 inflammation, and whether or not that will cause or 19 19 it may or may not. People are different. predict pain in a patient is not yet described? 20 BY MS. BYARD: 20 MR. ORENT: Objection. 21 Q. And so you can look at a slide of 21 THE WITNESS: It is described in other 22 22 mesh, with scar tissue, and see a nerve grown into areas. It's a general knowledge of what they 23 it, and you can't predict whether that patient had 23 accumulated. I mean, does inflamed knee hurt? I 24 pain, can you? 24 mean, what do you think? It's not just described, 25 25 it is a general knowledge. Something is inflamed, A. I can say that there is Page 147 Page 149 1 probability, there is mechanism for pain in that 1 it may hurt. 2 specific, if patient have or didn't have pain, this 2 BY MS. BYARD: 3 3 may depend on different circumstances. It may not Q. Do you know whether 100 percent of 4 hurt today, but it has probability it may hurt patients with edema present in their mesh and the 5 5 tomorrow. tissues surrounding their mesh will feel pain? 6 б A. What's percentage of those who So this would be, again, complex. And 7 it's not just for a nerve. If there is a nerve 7 have edema or don't have edema? I don't know exact 8 8 percentage. And I don't think it matters, because ingrown in the tissue, it means that the tissue is 9 9 alive. It can sense pain. So this is the it might be multiple mechanisms. 10 10 baseline. Then, pain can occur at any time there. So their pathological findings which 11 You add extra stimuli for pain, damage to the 11 are normal, and the degree of their contribution to 12 12 pain development is hard to predict because it's so tissue, inflammation, edema -- the more you add, 13 the probability goes higher and higher. But, 13 complex. 14 14 Q. And not yet known? again, you may have just a nerve ingrowth and it 15 gets tugged, and you have mechanism of pain right 15 MR. ORENT: Objection. 16 away. So this is so complex, and a variable 16 THE WITNESS: What do you mean, "not 17 between people, we cannot apply a specific --17 yet known?" We know that inflamed tissue hurts. 18 18 now I'm --BY MS. BYARD: 19 19 Q. But the rates at which it will Q. It's not predictable? 20 20 MR. ORENT: Objection. occur -- for instance, with edema, you can't tell 21 21 THE WITNESS: No, this is not true. me the rates at which pain will occur or --22 22 A. The main question is, it can It's predictable. If you have nerve ingrowth, you 23 have baseline for pain development. 23 happen. If it happens in the patient, you know why 24 24 So, once you have innervation of the this is happening. Assuming, if an area in the 25 tissue, pain can develop. If you don't have 25 body hurts, and you take a biopsy, and you see

	Page 150		Page 152
1	inflammation in there, but you don't see anything	1	many points of contact with other agencies, not
2	else, what would be your logical conclusion, why	2	everything is disclosed, or authors decide for that
3	did it hurt? Because it was inflamed and you don't	3	specific study there is no conflict of interest.
4	see anything else.	4	It's more up to the discretion of the author.
5	The same with meshes. Meshes hurt;	5	Q. But all things being equal, the
6	they come out. There is no tumor in it, there is	6	better course would be if the bias might affect the
7	no informal carcinoma, but there is nerve ingrowth,	7	subject of study, to disclose that conflict of
8	there is mesh, there is scarring.	8	interest, right?
9	Therefore, the only reason for it to	9	A. Yes
10	hurt is mesh-related changes. But the degree of	10	MR. ORENT: Objection.
11	contribution of how much inflammation contributed,	11	THE WITNESS: it's the best sort of
12	how much edema contributed, is difficult to	12	scientific practice. Not practice, but
13	predict. It has been studied in other areas. It	13	BY MS. BYARD:
14	was not studied in specific details in meshes.	14	Q. It's important for authors in the
15	Q. Thank you.	15	scientific and medical community, to disclose
16	Let me check the time.	16	conflict of interest?
17	MS. BYARD: Do you guys have steam for	17	MR. ORENT: Objection.
18	another article before we break for lunch?	18	THE WITNESS: It's important for
19	THE WITNESS: I have to go to the	19	readers to know if there's potential conflict of
20	washroom.	20	interest, yes.
21	MR. ORENT: Why don't we take five.	21	BY MS. BYARD:
22	THE VIDEOGRAPHER: Off the record at	22	Q. So, at this point, you have been
23	12:24 p.m.	23	deposed, I think we had the number at around seven
24	RECESS AT 12:24	24	or eight times in litigation where you've testified
25	UPON RESUMING AT 12:40	25	as an expert against mesh manufacturers, right?
	Page 151		Page 153
1	THE VIDEOGRAPHER: We're back on the	1	
1 2	THE VIDEOGRAPHER: We're back on the record at 12:40 p.m.	1 2	A. That's correct.
2	record at 12:40 p.m.	2	<ul><li>A. That's correct.</li><li>Q. And you've never once testified</li></ul>
2	record at 12:40 p.m. BY MS. BYARD:	2 3	A. That's correct. Q. And you've never once testified for a defendant manufacturer in a medical device
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39 (Pages 150 to 153)

Page 154 Page 156 A. Payment is not the only bias, I 1 BY MS. BYARD: 1 2 Q. You're paid by plaintiffs for your 2 will mean only other bias. I mean it's just what 3 3 you consider. But people may be biased by time? 4 MR. ORENT: Objection. 4 something else. 5 5 THE WITNESS: Sometimes, like today, I EXHIBIT NO. 1198: International 6 don't know, maybe you will pay for that, I mean --6 Scholarly and Scientific Research & 7 I actually sometimes don't know where the money 7 Innovation, 2014, Publication entitled, 8 8 comes from. There's so many people involved. "Pathology of Explanted Transvaginal 9 BY MS. BYARD: 9 Meshes," by Dr. V. Iakovlev, 10 Q. And while there's nothing -- I 10 Dr. E. T. Carey and Dr. J. Steege. 11 guess returning to my question about disclosures. BY MS. BYARD: 11 There's nothing that prevents an author from 12 12 Q. Doctor, do you recognize 13 providing disclosures of conflicts of interest if 13 Exhibit 1198? 14 the author feels that's important, right? 14 A. Yes, it's a paper I co-authored. 15 A. For full articles, it's usually a Q. Dr. Erin Teeter Carey is an expert 15 whose time is paid for by the Plaintiffs in the 16 requirement, but sometimes for abstracts, I mean, 16 17 then you don't know where to squeeze it, if there 17 mesh litigation; isn't she? 18 is no line when you submit it. So for abstracts A. Yes. 18 19 there may be no space to put this disclosure. 19 Q. And Dr. John Steege is a paid 20 So if I don't have that space, while 20 Plaintiffs' expert too, right? 21 submitting an abstract, I insert a slide disclosing 21 A. Yes. 22 that I've been consulting for medical-legal cases. 22 Q. And you were in fact introduced to I don't remember single time when I never -- when I 23 23 Dr. Erin Teeter Carey and Dr. John Steege by 24 have not disclosed it. 24 Margaret Thomson, a lawyer for the Plaintiffs, 25 Either way, I will find a way how to 25 right? Page 155 Page 157 disclose it. Either during presentation or during 1 A. Yeah. I think first contact was 1 2 abstract submission, or any other way. 2 during a conference call, and I think Dr. Thomson 3 Q. Were all the publications that you 3 was either participant or organizer of that call. 4 have authored on transvaginal mesh published in 4 Q. She was acting as a lawyer during 5 5 that conference call, correct? 2014? 6 A. Yes. 6 MR. ORENT: Objection. At this point, 7 7 Q. And the articles that you've I'm going to instruct the witness not to answer to 8 the extent that there are -- that this was as part 8 authored on transvaginal mesh have direct bearing on the reasons for your opinions in the lawsuit, 9 9 of a case consultation or work. 10 10 right? You can answer to the extent that you 11 11 MR. ORENT: Objection to form. had any conversations with the four of those people 12 THE WITNESS: It's kind of -- I 12 related to non-litigation work. BY MS. BYARD: 13 wouldn't word it like this. I considered all the 13 14 knowledge extracted during, doing this research 14 Q. Dr. Margaret Thomson was on the 15 project in formulating my opinions in these 15 call in her capacity as a lawyer, not in her 16 reports, yes. 16 capacity as a medical doctor, right? MR. ORENT: Objection. 17 17 BY MS. BYARD: 18 18 THE WITNESS: I don't know. She's a O. Well, and in fact, in all of the 19 19 publications that you authored, that came out this doctor and a lawyer, I mean, what capacity she's year, you included information that you identified 20 20 serving in... 21 during your work as a paid expert for the 21 BY MS. BYARD: 22 22 Plaintiffs, correct? Q. You were paid for your time on 23 A. Yes. As I said, I mean, I 23 these conference calls by Plaintiffs' lawyers or 24 disclose it every time I can. 24 their firms, right? 25 Q. Let's mark 1198. 25 MR. ORENT: Objection.

40 (Pages 154 to 157)

	Page 158		Page 160
1	THE WITNESS: I don't think I	1	significance? I didn't hear you.
2	specifically charged for all these conference calls	2	A. The degree of statistical
3	or contacts. It depends, I mean, it's	3	significance is not either assessed, or is not
4	BY MS. BYARD:	4	95 percent, or there are other factors which
5	Q. You weren't there in conjunction	5	introduce the degree of unknown factors.
6	with your work as an anatomical pathologist at	6	Q. Okay. So here, for whether or not
7	St. Michael's, though, right?	7	the pathological examination explains mechanisms of
8	MR. ORENT: I'm going to now instruct	8	complications resulting in product excision, which
9	the witness this is all covered by Rule 26	9	one of those factual scenarios that you described
10	privileges. So if you want to ask questions	10	applied? Is that, is it that there was not an
11	related to his work on these papers, I'll let him	11	assessment of statistical significance? Was it
12	answer anything related to the papers. But if	12	that there was other confounding factors, or that
13	you're asking about his specific relationship with	13	the degree of significance was not statistically
14	Plaintiffs, Plaintiffs' experts and trial strategy	14	the degree of difference was not statistically
15	meetings, I'm going to specifically instruct him	15	significant?
16		16	-
	not to answer.	17	MR. ORENT: Objection. THE WITNESS: No, neither. Because
17	BY MS. BYARD:		, ·
18	Q. Are you going to follow Counsel's	18	this states a hypothesis, so before we started, we
19	instruction?	19	examined and we had a hypothesis made. So it was
20	A. As I said initially, I had first	20	this statement describes state of the research
21	contact	21	project before the research project.
22	MR. ORENT: I only want you to answer	22	BY MS. BYARD:
23	as to the extent that you can answer without	23	Q. Okay. So let's look at the
24	revealing any trial strategy meetings you may have	24	discussion on page 508. The last paragraph of the
25	attended, or anything related to your consultation	25	discussion ends after discussion of nerve
	Page 159		Page 161
1	related to Plaintiffs in this litigation.	1	entrapment and compression, stretching, edema,
2	THE WITNESS: Okay.	2	ischemia.
3	BY MS. BYARD:	3	It says: "The roles of these
4	Q. Let's take a look at the abstract	4	mechanisms need to be further studied," doesn't it?
5	of this published article conceived in a conference	5	
6	or and published article content to in a complete	~	A. Yes. Exactly which part of can
1	call with Plaintiffs' counsel.	6	A. Yes. Exactly which part of can you point?
7	÷		
7 8	call with Plaintiffs' counsel.	6	you point?
	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to	6 7	you point?  Q. Yes, yes. Excuse me. The last
8	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.	6 7 8	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under
8 9	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:	6 7 8 9	you point? Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".
8 9 10	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:  Q. It says:	6 7 8 9	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".  A. Yes, I can see it.
8 9 10 11	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:  Q. It says:  "We aimed to perform a thorough	6 7 8 9 10 11	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".  A. Yes, I can see it.  Q. And I read that correctly, right?
8 9 10 11 12	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:  Q. It says:  "We aimed to perform a thorough pathological examination of	6 7 8 9 10 11 12	you point? Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion". A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms
8 9 10 11 12 13	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD: Q. It says:  "We aimed to perform a thorough pathological examination of explanted POP meshes and describe	6 7 8 9 10 11 12 13	you point? Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion". A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms need to be further studied." Yes, that is correct.
8 9 10 11 12 13	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:  Q. It says:  "We aimed to perform a thorough pathological examination of explanted POP meshes and describe findings that may explain mechanisms	6 7 8 9 10 11 12 13 14	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".  A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms need to be further studied." Yes, that is correct. Q. The conclusory sentences of the
8 9 10 11 12 13 14 15	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD:  Q. It says:  "We aimed to perform a thorough pathological examination of explanted POP meshes and describe findings that may explain mechanisms of complications resulting in	6 7 8 9 10 11 12 13 14	you point? Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion". A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms need to be further studied." Yes, that is correct. Q. The conclusory sentences of the next paragraph read:
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8 9 10 11 12 13 14 15 16 17 18 19 20	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD: Q. It says:  "We aimed to perform a thorough pathological examination of explanted POP meshes and describe findings that may explain mechanisms of complications resulting in product excision."  Do you see that?  THE WITNESS: Yes, I do.  BY MS. BYARD: Q. And again, we see that word "may"	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".  A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms need to be further studied." Yes, that is correct. Q. The conclusory sentences of the next paragraph read:  "Polypropylene degradation may play a role in the continuous inflammatory response mesh hardening and light deformations."  Did I read that correctly?
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	call with Plaintiffs' counsel.  MR. ORENT: And I'm going move to strike that comment as without foundation.  BY MS. BYARD: Q. It says:  "We aimed to perform a thorough pathological examination of explanted POP meshes and describe findings that may explain mechanisms of complications resulting in product excision."  Do you see that?  THE WITNESS: Yes, I do.  BY MS. BYARD: Q. And again, we see that word "may" there, don't we?  A. Yes. This is a commonly accepted	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	you point?  Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".  A. Yes, I can see it. Q. And I read that correctly, right? A. "The roles of these mechanisms need to be further studied." Yes, that is correct. Q. The conclusory sentences of the next paragraph read:  "Polypropylene degradation may play a role in the continuous inflammatory response mesh hardening and light deformations."  Did I read that correctly?  THE WITNESS: That's correct. BY MS. BYARD:

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Page 162
                                                                                                        Page 164
 1
              their composition and effect on the
                                                             1
                                                                  ingrowth, then degradation itself, how much of one
 2
              tissue."
                                                             2
                                                                  of those contribute and so on. It's, again, degree
 3
                                                             3
              Did I read that correctly?
                                                                  of uncertainty.
                                                             4
 4
              A. That is correct.
                                                                         Also, degradation is continuous
 5
              O. And then in the last sentence of
                                                             5
                                                                  process, so it will build up over the years, in the
 6
                                                             6
      the last paragraph of the discussion, it says:
                                                                  beginning so -- there's a degree of uncertainty
 7
                 "We believe that these
                                                             7
                                                                  between all of those. I mean, what we know, it
                                                            8
 8
              specimens contain information of the
                                                                  degrades, and with what we know, it hardens. So
                                                            9
 9
              mechanisms of complications and
                                                                  these are the two points which we know for sure.
                                                           10
10
              further study may help guide future
                                                                         But the degree of connection and the
11
              development of treatment modalities."
                                                           11
                                                                  complex interaction between these factors is not
12
              Did I read that correctly?
                                                           12
                                                                  studied to details. Therefore, in scientific
13
              A. That's correct.
                                                           13
                                                                  literature the word "may" is used.
                                                           14
14
                                                                         Q. What this discussion doesn't say
              Q. And it says:
                                                           15
                                                                  is that the tissue findings that you have observed
15
                 "These are previously
16
              unreported findings."
                                                           16
                                                                  in transvaginal mesh causes pain through the
17
              In the first sentence of that
                                                           17
                                                                  mechanisms that you've described?
                                                           18
                                                                         A. Where does it say?
18
      paragraph, right?
                                                           19
19
              A. Some of the findings were
                                                                         Q. Well, I'm saying, nowhere does
20
      previously unreported, yes, that's correct.
                                                           20
                                                                  this discussion conclude that, does it?
21
              Q. And again, was this language "may"
                                                           21
                                                                         A. It wasn't the purpose of the
22
                                                                  study. Just read the title: "Pathology of
      used here because the statistical -- a
                                                           22
23
      statistically significant difference was not
                                                           23
                                                                  Explanted Transvaginal Meshes."
24
      assessed between controlled samples in the study?
                                                           24
                                                                         It was a descriptive study describing
25
                                                           25
              MR. ORENT: Objection.
                                                                  the findings.
                                             Page 163
                                                                                                        Page 165
 1
                                                             1
             THE WITNESS: You have to point exact
                                                                         Q. Okay. And, again, this article
 2
      sentence. Which, which "may"?
                                                             2
                                                                  doesn't even go so far as to say that mesh could
 3
             BY MS. BYARD:
                                                             3
                                                                  cause pain through the -- through these tissue
                                                             4
 4
             Q. "Polypropylene degradation may
                                                                  response mechanisms that you've described?
                                                             5
 5
             play a role in the continuous
                                                                         MR. ORENT: Objection.
 6
             inflammatory response, mesh
                                                             6
                                                                         THE WITNESS: Again, this was not the
                                                             7
 7
             hardening and late deformations."
                                                                  purpose of this study. Purpose of this study, if
 8
                                                            8
             A. Yes, so let me see. I have to
                                                                  you read the abstract is, meshes cause
 9
      read the whole paragraph.
                                                            9
                                                                  complications. This triggers excision, and they
10
                                                           10
                                                                  have not been studied as to find reasons and
             Q. Okay.
                                                           11
11
             A. (Witness reviews document).
                                                                  mechanisms of the complications.
12
             Yeah, this is a combination. See,
                                                           12
                                                                         So the purpose of this was to study and
13
      inflammatory response, mesh hardening and late
                                                           13
                                                                  see what is pathological in those specimens,
14
      deformations.
                                                           14
                                                                  abnormal. And then these abnormalities can be
15
             This is observations which we have.
                                                           15
                                                                  described and documented.
16
      But the degree of connection between degradation
                                                           16
                                                                         And then the next step would be to
17
      and each of this is different.
                                                           17
                                                                  split specimens according to specific complications
18
                                                                  and see statistically what each of those specific
             For example, if we go to continuous
                                                           18
                                                           19
19
      inflammatory response, we would have to study exact
                                                                  pathology co findings contribute, and what's the
      chemicals which are produced during degradation.
                                                           20
20
                                                                  interaction between them. So it's study details of
21
      And how these chemicals may modify inflammatory
                                                           21
                                                                  all this.
22
      response and other thing, this is unknown.
                                                           22
                                                                         BY MS. BYARD:
23
      Therefore, it introduces a degree of uncertainty.
                                                           23
                                                                         Q. And that second step that you've
24
             Mesh hardening -- there will be
                                                           24
                                                                  described wasn't done here?
25
      different mechanisms for mesh hardening, scar
                                                           25
                                                                         A. No.
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Page 166 Page 168 1 Q. And it hasn't been done by you? 1 Q. Okay. We can do that in a second. 2 A. I'm in the process of doing, 2 Looking back here at the "Materials and 3 3 studying the small details of these things. Methods Section," if you would, Doctor. 4 Because for each specific finding, 4 A. Yes. 5 there is a degree of knowledge we have in pathology 5 O. You write: 6 6 and overall in general. I mean, even for common "In total, 24 specimens of 7 person, if vessel is obstructed, you know, there 7 St. Michael's Hospital patients and 8 8 will be no bleed going through it. It doesn't need external consultation cases from 9 further studying. 9 litigation processes have been 10 But how does it get obstructed? Is it 10 analyzed." 11 because there is a slowing down of the blood in 11 Did I read that correctly? 12 there? Or because it's chemical issues affecting --12 A. That's correct. 13 a chemical product of degradation, which is 13 Q. What does, "external consultation 14 affecting blood or blood vessel, that makes it 14 cases from litigation processes" mean? 15 15 A. Litigation cases. clot. 16 All these details will have to be 16 Q. These lawsuits we're here to talk 17 studied. I'm surprised it wasn't for 50 years, 17 about today, as well as the ones involving other 18 because the findings are there. 18 manufacturers? 19 Q. Right, and that's a fair point. I 19 A. Yes. 20 mean, for 50 years, pathologists have looked at 20 Q. Why is the number here 24, when 21 polypropylene mesh, and no one has seen what you 21 we -- in your report we have 120? 22 have seen and reported here, which is 22 A. For that specific number -- first 23 degradation --23 of all, let's see if it was -- see, it was limited 24 MR. ORENT: Objection. 24 to POP first. It was limited to those -- I could 25 BY MS. BYARD: 25 get exact information at that point, it was entered Page 169 Page 167 1 O. -- right? 1 in the spreadsheet. So at that point, I had 2 A. Have they been looking at all 2 verified reliable data, which was on the 3 meshes? Have they been looking to answer the 3 spreadsheet for those 24 only POPs. 4 questions of complications? I mean... 4 Again, this was started much earlier 5 5 Q. My question is simpler: No one before 120. The paper became published maybe half 6 else has reported having seen what you see. б a year after the study was pretty much done. 7 MR. ORENT: Objection. That misstates 7 Q. So at the time that you submitted 8 8 this report for publication, you only had the the record. THE WITNESS: That's not true. I mean, 9 completed verified data set or 24 POP specimens; is 9 10 10 that right? there are papers which are stating some of the 11 11 findings. MR. ORENT: Objection. Like polypropylene degradation, it was 12 THE WITNESS: With all information, I 12 13 13 first described in the '70s. There's a degree, would need to include it in the study, yes. It my 14 there are different methods. Sometimes it's not 14 be for some samples I didn't have exact information 15 15 the primary purpose of the study, but in if it was POP or sling or something else. 16 combination, these findings were mentioned in many 16 BY MS. BYARD: 17 papers. 17 Q. If we were going to consider the 18 18 BY MS. BYARD: 120 specimens that are in your report for inclusion in this study, how many would meet the criteria? 19 19 Q. By pathologists? A. Pathologists -- you mean scientist 20 20 And let's say for purposes of this 21 21 pathologists or diagnostic pathologists? evaluation, that the study is not limited to POP, 22 Q. Either. 22 but includes SUI product? 23 A. I don't know. We would have to 23 MR. ORENT: I just want to object to 24 24 your use of the term, "120 cases included in your look at each paper and see what's the credentials 25 included, and what exactly is described there. 25 report."

43 (Pages 166 to 169)

Page 170 Page 172 1 I want to make clear, what Dr. Iakovlev 1 lightweight mesh, how many samples of each were 2 is talking about on page 2 of his report is his 2 included in these 24. You have examples of what 3 3 experience, and then he goes on to talk about his area focally of the mesh was filled with loose 4 4 connective tissue. You have statistics on the education and training. 5 5 His opinions are based on his number of specimens that showed neural ganglia 6 6 experience, education and training; but are not involvement. 7 based specifically on any one sample or samples. 7 I'm just trying to understand if all of 8 8 And I think you're confusing him. It's not a those same data points have been obtained and exist 9 9 report on 120 cases that he's offered here. in the spreadsheet, or however you keep it, for the 10 10 MS. BYARD: Counsel, again, the 120 specimens that are referenced in your report? 11 speaking objections are not --11 MR. ORENT: Objection. 12 12 MR. ORENT: That's not an objection. THE WITNESS: This data is obtained for 13 That's a clarification for the record. 13 all specimens which are completed, which excision 14 14 is completed with surgical pathology report. MS. BYARD: I'm asking him about his 15 As you saw, as I mentioned, the 15 data set, which are specimens, which are what my 16 16 surgical pathology report includes all of this questions are directed to. 17 THE WITNESS: I can answer that 17 because I examine all specimens according to question. 18 standardized protocol. 18 19 19 All findings described in this paper So all of the findings which are 20 could be seen in those 120 or larger number of 20 described are even more since then are recorded, 21 specimen. I see them over and over again. 21 assessed, either they're there or they're not 22 22 BY MS. BYARD: there. 23 23 Q. But you don't have -- you don't How many of those have been completed, 24 have this completed data set that you had on these 24 likely close to 100, but I haven't updated it 25 25 recently because of an avalanche of work recently. 24 specimens on all 120? Page 171 Page 173 1 A. We'll deal in data set. It's not 1 BY MS. BYARD: 2 a data set, it's a descriptive study which is 2 Q. Here under "Results," you mention 3 describe what findings we could find. There is no 3 that: 4 statistics in it, if you can see --4 "Available clinical records I mean, there is statistics of 5 5 indicated mucosal exposure as a 6 frequencies in this specific 24. 6 reason for excision in 67 percent of 7 7 Q. Right. cases -- " do you see that? 8 A. But it's not a comparison between 8 A. Yes. 9 what happens in those who experience these type of 9 Q. And: 10 10 complication and the other one. "Pain in 56 percent of cases, 11 and both, in 33 percent of cases." I mean, as I said, if we take generally 11 12 the purpose of this study, pathology of explanted 12 A. Correct. 13 transvaginal meshes so -- and it was specifically 13 Q. You also say that the product --14 focused on POP devices. 14 these 24 specimens, include products from three 15 If I take all of the POP devices I 15 different manufacturers; do you see that? 16 examined, there will be no -- all of these findings 16 A. Yes, I do. 17 can be seen there. And all of them can be 17 Q. Which were the three 18 included, and if you're trying to ask me if I 18 manufacturers? 19 selected them specifically, no. I can expect these 19 A. The earliest I received was AMS, 20 findings in any POP devices. 20 and then you, and then probably Ethicon. 21 21 Q. Actually, what I'm trying to Q. Okay. So the study includes 22 understand, Doctor, is whether the data that you 22 Boston Scientific devices? 23 had to complete this study. So, for instance, here 23 A. By the time of this study, likely. 24 24 Q. Is there something you can check you have descriptions of the fragment size. You 25 have descriptions of the heavyweight versus 25 to confirm that for me?

44 (Pages 170 to 173)

1 A. Yes, I should be able to do that. 2 MS. BYARD: Okay. We need to go off 3 the record to change the tape. 4 THE VIDEOGRAPHER: This marks the end 5 of media number two in the deposition of 6 Dr. Vladimir Iakovlev. 1 THE WITNESS: That's correct 2 BY MS. BYARD: 3 Q. You were a paid expert for this report, right? 5 this report, right? 6 A. Yes.	
2 MS. BYARD: Okay. We need to go off 3 the record to change the tape. 4 THE VIDEOGRAPHER: This marks the end 5 of media number two in the deposition of 5 MS. BYARD: 3 Q. You were a paid expert for this report, right? 5 this report, right?	
the record to change the tape.  THE VIDEOGRAPHER: This marks the end of media number two in the deposition of  THE VIDEOGRAPHER: This marks the end this report, right?	
4 THE VIDEOGRAPHER: This marks the end 5 of media number two in the deposition of 5 this report, right?	the
5 of media number two in the deposition of 5 this report, right?	
	F
11. 100	
7 We are going off the record at 7 Q. And you continue to be one	today?
8 1:08 p.m. 8 A. Yes, I am.	
9 OFF THE RECORD DISCUSSION 9 Q. That relationship hasn't stor	pped
THE VIDEOGRAPHER: Here begins media 10 since it began?	
11 number three in the deposition of Dr. Vladimir 11 MR. ORENT: Objection.	
12 Iakovlev. 12 THE WITNESS: No, but you n	nade it sound
We're back on the record at 1:09 p.m. 13 as if it's my full-time job.	1000110
14 Go ahead, Counsel. 14 BY MS. BYARD:	
15 MS. BYARD: Thank you. 15 Q. I didn't mean to imply that.	What
16 BY MS. BYARD: 16 percentage of it is your income?	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
2 Prince of the system of the	
18 if I said this actually, let me withdraw that. 18 completed billing, and I haven't last y	ear it
Here, if we turn to "Disclosures", Doctor. 19 was less than 10 percent.	cui it
20 This reads: 20 Q. And this year do you have a	n
21 "Authors provided medical-legal 21 estimate of what percentage litigation c	
22 consultations on the subject." 22 work for Plaintiffs will make of your over	-
23 A. Yes. 23 income?	Clair
24 Q. At the time you published this 24 A. Probably more than last year	nr
25 article, you were working as a paid expert for 25 likely more than 10 percent. But how n	
	Page 177
1 Plaintiffs, right? 1 don't know. Less than 50 percent, anyw	
2 MR. ORENT: Objection. 2 10 to 50 percent, any whole the second	nere between
THE WITNESS: No, I was working as a Q. Here, though, in your disclose	sure
4 pathologist at St. Michael's Hospital. But I  4 it doesn't say which side your consulting	
5 provided consultations, and I was paid for time I 5 on, does it?	, work was
6 spent for consultations.  6 MR. ORENT: Objection.	
7 BY MS. BYARD: 7 THE WITNESS: No. But shoul	d I bias
8 Q. At the time that you published 8 readers, or just tell them that I may be bi	
9 this report, you were still acting as a retained 9 Because if I start disclosing then, further	
10 expert for Plaintiffs, right?  10 details, I introduce extra bias.	
11 MR. ORENT: Objection. 11 BY MS. BYARD:	
THE WITNESS: What do you mean 12 Q. Well, it could cause some au	thors
13 "acting"? I mean, my main job is pathologist at 13 to discredit your some readers to discredit	
14 St. Michael's Hospital and assistant professor at 14 work, because they know that your work	
the University of Toronto. I do provide 15 side versus the other; is that what you're	
16 medical-legal consultations when asked. 16 MR. ORENT: Objection.	, ,
17 BY MS. BYARD: 17 THE WITNESS: It's up to reade	rs to
Q. Your relationship, your consulting 18 decide if there is a bias in the paper. I ju	
relationship with Plaintiffs' counsel, hadn't ended 19 provide them this information that I may	
by the time this report was published, right? 20 bias. Which way and how I mean, I can	
21 MR. ORENT: Objection. 21 criticizing specific type of mesh and wor	
22 THE WITNESS: That's correct. 22 another manufacturer, who is trying to so	-
23 BY MS. BYARD: 23 polypropylene mesh. I mean, there migh	
24 Q. It was ongoing? 24 multiple biases.	

45 (Pages 174 to 177)

Page 178 Page 180 1 biased in this paper, and I disclose it. 1 Q. Peers, just picking up this 2 BY MS. BYARD: 2 article, this article alone, wouldn't know that you 3 3 Q. It sounds like this is something have testified for plaintiffs against mesh 4 4 manufacturers in seven depositions and at two you've thought about this before? 5 5 A. What do you mean? trials, would they? 6 6 Q. Did you make a conscious decision MR. ORENT: Now you're misrepresenting 7 about whether or not to include that it was for one 7 the timeline and facts of this case and being 8 8 side versus the other that you were doing this argumentative. 9 9 consulting work? THE WITNESS: I just don't understand 10 MR. ORENT: Objection. 10 where you would see that somebody would list all 11 THE WITNESS: I always approach 11 the depositions and everything else in disclosure. 12 everything trying to be as neutral as possible, and 12 Disclosure, as I said, if it's funded, 13 give neutral information. I mean, it's always in 13 usually the funding agencies provide it. 14 14 If there are other conflicts of my head. 15 15 BY MS. BYARD: interest, they just provide it through best sort of 16 16 Q. So did you have a discussion with neutral, or shortest way, or depending on the 17 Dr. Carey and Dr. Steege about whether you should 17 paper. 18 put which side your consulting work was on? 18 This paper wasn't funded by anyone. I 19 A. No, I don't remember if we 19 received the specimens from different sources, and 20 discussed the specifics. I mean, usually, it's 20 we analyzed it, and there was no additional work to 21 disclosed conflict of interest, and people describe 21 what usually pathology laboratory does. 22 22 them as the way they think is most appropriate. BY MS. BYARD: 23 Sometimes journal has specific requirements, how 23 Q. So the words "for plaintiffs" does 24 vou describe it. 24 not appear in this disclosure, right? 25 25 MR. ORENT: Objection. Q. So, for instance, if a study -- a Page 179 Page 181 clinical study, let's say, was funded by Boston 1 THE WITNESS: No. And, essentially, it 2 Scientific, it would indicate that it was funded by 2 was part of the purpose not to bias it in this way. 3 Boston Scientific, if the author was following, 3 As I said, there might be multiple 4 what you've described as the best practices, right? 4 biases. Plaintiff, not plaintiff, the manufacturer 5 MR. ORENT: Objection. 5 can be presenting different type of biases. 6 THE WITNESS: If a study is funded by a 6 Plaintiffs have claims that it caused 7 7 specific agency, there might be a specific damage. But at the same time, there might be 8 8 question. another manufacturer which can introduce bias. As When you submit it, it might be just a 9 9 I said, there's two types of devices on the market 10 drop-down menu. Was it funded by someone; by whom? 10 and so forth. There might be multiple biases. BY MS. BYARD: 11 Then you have to disclose it. 11 12 If it's a free text, what you disclose, 12 Q. As a reader, someone could not 13 you can say that funding came from this, this and 13 tell which type of multiple biases that are 14 that agency. And then readers can decide if it can 14 possible could have influenced your writing on the 15 have a bearing on the conclusions. 15 subject? 16 BY MS. BYARD: 16 MR. ORENT: Objection. 17 17 Q. How common is it for you to see a THE WITNESS: That's not the point. 18 disclosure that says, "this research was funded" 18 The point is that to disclose that there might be 19 19 without any indication as who the funding was from? bias. And -- if you are funded by an agency, 20 A. What do you mean "funded"? 20 assuming. So, you assume that that agency has --21 Usually when it's funded it says a grant or 21 either doesn't or has some control of what is being 22 something else agency. 22 published and what is not being published. 23 Q. The disclosure tells you who 23 But it's not included in the statement; 24 funded? 24 it just states what's the agencies. It's up to 25 A. Yes. But this study wasn't funded. 25 readers to think if it could have an affect on the

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Page 182
                                                                                                       Page 184
 1
      researcher or couldn't.
                                                            1
                                                                        THE WITNESS: Have you ever seen --
 2
             So this is how it is done. It is
                                                            2
                                                                        BY MS. BYARD:
 3
                                                            3
                                                                        Q. Does the word appear there,
      disclosed to the most neutral way, and then it's up
                                                            4
 4
      to readers to see if the paper, paper itself,
                                                                 Doctor?
                                                            5
 5
      contains any information that it could have been
                                                                        A. No. it's not --
                                                            6
 6
      biased.
                                                                        MR. ORENT: Counsel, you're not
 7
                                                            7
                                                                 entitled to badger the witness. He's answered your
             BY MS. BYARD:
                                                            8
 8
             Q. And part of how you evaluate that
                                                                 question four times. You're trying to clearly get
 9
      is by knowing who funded the study?
                                                            9
                                                                 your bullet point, you can read the article just as
                                                          10
10
             MR. ORENT: Objection.
                                                                 well as any of us.
11
             THE WITNESS: No, no. Not exactly.
                                                          11
                                                                        The Rules of Civil Procedure do not
12
             BY MS. BYARD:
                                                          12
                                                                 permit badgering of the witness, so move on.
13
             O. Part of the way that you do that
                                                          13
                                                                        MS. BYARD: It's my deposition and I'm
14
      is knowing who prior consulting work was for?
                                                          14
                                                                 entitled to get answers to my questions.
15
             MR. ORENT: Objection.
                                                          15
                                                                        BY MS. BYARD:
16
                                                          16
              THE WITNESS: I would say not who
                                                                        Q. My question is simply this, Doctor:
17
      funded the study, but if the funding agency could
                                                          17
                                                                        Under the disclosure, in your study
18
      have an effect or control on the researchers,
                                                          18
                                                                 with Dr. Carey and Dr. Steege, it says, "authors
19
                                                          19
                                                                 provided medical-legal consultations on this
      that's the most important question.
20
             I mean, most of the clinical studies or
                                                          20
                                                                 subject." It does not say "for plaintiffs," does
21
      other are funded, because it's such an expensive --
                                                          21
22
                                                          22
      but then it's up to readers to see if funding
                                                                        A. No, it does not --
23
      agency could control, could have an effect. It may
                                                          23
                                                                        MR. ORENT: Objection.
24
      be not direct.
                                                          24
                                                                        THE WITNESS: -- state. I could have
25
                                                          25
                                                                 been providing for both Plaintiffs and
             I mean, like you focusing on
                                            Page 183
                                                                                                       Page 185
 1
      manufacturers. But there are some non-for-profit
                                                            1
                                                                 manufacturers.
 2
      organizations which are funding with grants and
                                                            2
                                                                        BY MS. BYARD:
 3
                                                            3
      everything else, and there is a competition to get
                                                                        Q. As a reader, I would have no way
 4
      these grants and so forth. So you might be biased
                                                                 of knowing which side your testimony had been paid
                                                            5
 5
      to produce better results in order to renew a grant
                                                                 for by reading your article?
 6
      and so forth.
                                                            6
                                                                        MR. ORENT: Objection.
 7
              So this is a different bias. It might
                                                            7
                                                                        THE WITNESS: You shouldn't have to
                                                            8
 8
      be even stronger than just financial bias. It's
                                                                 know. You should be able to go through the paper
                                                            9
                                                                 and try to find clues if there was a bias. Because
 9
      the same financial bias, because you are acquiring
                                                          10
                                                                 that's the whole point of critical appraisal in the
10
      grants from there. Again, it's up to the readers
      to decide if that specific funding agency could
                                                          11
11
                                                                 literature.
12
                                                          12
                                                                        If somebody tells you from the
      have an effect.
13
                                                          13
                                                                 beginning, that this study is biased because it was
             Medical-legal consultation means that
14
      somebody provided opinion and was paid. So this
                                                          14
                                                                 paid and so forth, would you read this article?
15
                                                          15
      can create a bias, and it's up to readers, again,
                                                                        BY MS. BYARD:
16
      go and see if there is any indication that there
                                                          16
                                                                        Q. Is that part of the reason why you
                                                          17
17
      was a bias. And I provided bias -- that, that
                                                                 didn't disclose which side you were on?
                                                          18
18
                                                                        A. No, I'm just saying that I never
      possibility.
                                                          19
19
             BY MS. BYARD:
                                                                 seen a single paper where the disclosure was
                                                          20
                                                                 formulated the way you're trying to introduce.
20
              Q. Let's see what we can agree on,
                                                          21
21
      because you've said a lot on this.
                                                                        I have never seen when it states that
22
                                                          22
              All I want to know is whether the word
                                                                 somebody was consulted on side of plaintiff. Maybe
23
      "for plaintiffs" appears in this sentence?
                                                          23
                                                                 they exist, but I've never seen it.
24
                                                          24
              MR. ORENT: Objection. That's been
                                                                        Q. Have you seen disclosures where it
25
      asked and answered.
                                                          25
                                                                 says, "doctor so and so provided consulting for
```

47 (Pages 182 to 185)

	Page 186		Page 188
1	such and such company"?	1	here.
2	MR. ORENT: Objection.	2	A. Coauthors. Yes, you read it
3	THE WITNESS: Usually it's financial	3	correct.
4	disclosure. "This funding was sponsored or funded	4	Q. Here there is a discussion of,
5	in part by this manufacturer" or something like	5	again, looking at specimens. This time of
6	this.	6	transvaginal slings; do you see that?
7	I don't remember specifically wording	7	A. Yes, this was limited to slings.
8	like you've just said. Usually they describe	8	Q. How many specimens were included
9	funding agency or manufacturer in terms of funding	9	in this write-up? I thought I saw 63 in Table 1.
10	source.	10	A. Yes. So a total number was 63,
11	EXHIBIT NO. 1199: Abstract entitled,	11	18 were retropubic and 45 were transobturator.
12	"Pathological Findings of Transvaginal	12	Q. Here, for the 63 studies, you used
13	Polypropylene Slings Explanted for Late	13	scar tissue from non-mesh excisions as a reference
14	Complications: Mesh is Not Inert," by	14	control?
15	Dr. V. Iakovlev, Dr. G. Mekel and Dr.	15	A. Just general understanding, how it
16	J. Blaivas	16	looks and what are the pathological findings, yes.
17	BY MS. BYARD:	17	Q. There wasn't any sort of objective
18	Q. I'm handing you Exhibit 1199.	18	measuring of the number of nerves, or the number of
19	And this is another publication of	19	blood vessels like we saw in your hernia mesh study
20	yours from this year, right, Doctor?	20	with Dr. Bendavid, right?
21	A. That's correct.	21	A. No. In this case, scar tissue was
22	Q. And this is an article that you	22	used more for a reference for inflammation, for
23	published with doctor I'm sorry an abstract	23	foreign body reaction and other mesh-related
24	that you published with Dr. Mekel and Dr. Blaivas,	24	changes.
25	right?	25	Q. I wanted to understand the
	Page 187		Page 189
1	A. That's correct.	1	
			sentence two, three lines in, under "Interpretation"
2	O. And Dr. Blaivas is a paid	2	sentence two, three lines in, under "Interpretation of Results" where you write:
3	Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right?	l .	of Results" where you write:
	Plaintiffs' expert, too, right?	2	of Results" where you write: "In contrast, mature scar
3	*	2	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does
3 4	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.	2 3 4	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."
3 4 5	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?	2 3 4 5	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that?
3 4 5 6	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the	2 3 4 5 6	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."  Do you see that?  A. So can you point where you
3 4 5 6 7	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?	2 3 4 5 6 7	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that?
3 4 5 6 7 8	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it	2 3 4 5 6 7 8	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."  Do you see that?  A. So can you point where you Q. Sure. Underneath "Interpretation
3 4 5 6 7 8 9	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of	2 3 4 5 6 7 8	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."  Do you see that?  A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in.
3 4 5 6 7 8 9	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.	2 3 4 5 6 7 8 9	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2.
3 4 5 6 7 8 9 10	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.  Q. So of the cases that you're aware	2 3 4 5 6 7 8 9 10	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar
3 4 5 6 7 8 9 10 11	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.  Q. So of the cases that you're aware of, he testified for the Plaintiffs?	2 3 4 5 6 7 8 9 10 11	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show
3 4 5 6 7 8 9 10 11 12 13	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the  Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.  Q. So of the cases that you're aware of, he testified for the Plaintiffs?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show inflammation." Yes, that's correct.
3 4 5 6 7 8 9 10 11 12 13 14	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.  Q. So of the cases that you're aware of, he testified for the Plaintiffs?  A. Yes.  Q. You write:	2 3 4 5 6 7 8 9 10 11 12 13 14	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show inflammation." Yes, that's correct. BY MS. BYARD:
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Plaintiffs' expert, too, right?  A. I know that he gave his opinion to some cases.  Q. For the Plaintiffs, correct?  A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.  Q. So of the cases that you're aware of, he testified for the Plaintiffs?  A. Yes.  Q. You write:  "Over the last decade polypropylene mesh slings have become the most commonly performed operation for stress incontinence."  Correct?  A. That's correct. Did I write where did I say (Witness reviews documents.)  In part. It could be part of my	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of Results" where you write:  "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show inflammation." Yes, that's correct. BY MS. BYARD: Q. What does "mature scar tissue" mean? A. Mature scar tissue. Scar tissue is mature. Q. Is there a point in time when scar tissue shows evidence of inflammation? A. When it's really early in its development. I mean, the first initial reaction to

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Page 190 Page 192 1 Q. And we don't really need to go 1 There are multiple differences between 2 into all that, because I do understand that from 2 a scar without mesh and a scar with mesh. 3 your deposition before. I appreciate that, thank 3 BY MS. BYARD: 4 4 you, Doctor. Q. In this discussion where you say, 5 5 What I'm trying to understand is when "scar tissue from non-mesh excisions were used as 6 in time you will stop seeing inflammation in the 6 reference controls," are you referring to the scar 7 development of scar tissue? 7 tissue that you used from the abdominal wall in the 8 Dr. Bendavid study, or were you specifically 8 A. Sometime after few weeks of 9 9 healing. referencing scar tissue from vaginal mesh 10 10 Q. How long will it take for nerves excisions? 11 to begin to ingrow in scar tissue? 11 A. In this case, specifically for 12 12 A. Also happens within first few vaginal mesh. I mean, they were not grouped 13 weeks of healing. 13 together, but either with the specimens, sometimes 14 14 Q. First few weeks -- are we talking I received just scar tissue without mesh outside. 15 one to four weeks, or are we talking one to 15 Sometimes it's just a scar excision and surgeon 16 six weeks? What's the window that's accepted? 16 identifies it as a scar excision. Or sometimes we 17 A. It's very variable. It depends on 17 receive it in the course of some surgeries in 18 individuals, conditions, repetitive injury. And 18 St. Michael's Hospital, so I visually know what it 19 19 all this process are continuing from about day looks like. 20 three to anywhere six, eight weeks, maybe longer. 20 Q. And then you go on to write that: 21 If there is continuous injury, it may repeat itself 21 "Surprisingly, easily visible 22 22 in the microscope, it has been during years. 23 23 Q. So if a patient, for instance, overlooked for 50 years." 24 complained of immediate postoperative pain, would 24 And there you're describing what you've 25 it be fair to say that nerve ingrowth in mesh 25 coined as a term, "degradation bark"; right? Page 191 Page 193 structures could not be the source of that pain, 1 1 A. Yes, that's correct. The 2 because nerves could not yet appear growing within degradation layer was not described as it appears 3 3 in the light microscope. the mesh structure? 4 A. Yes, that's correct. 4 Q. And that's what I was getting at 5 5 Q. Okay. And here you talk about earlier. On the one hand you told me degradation 6 potential sources of pain, you write: 6 of polypropylene has been described since the 1970s. And then here, in this abstract that you 7 "Within these mini compartments, 7 8 8 the innervated tissue is exposed to publish with Dr. Blaivas, you say it's been potential sources of pain such as 9 9 overlooked for 50 years? I was trying to reconcile 10 10 compression, stretching, that. 11 inflammation, ischemia, etcetera." 11 A. Well, it's clear. This states 12 A. That's correct. 12 about microscopic appearance and the cross-sections 13 13 Q. But you would agree these in a light microscope, and I'm talking about 14 potential sources of pain are also present in scar 14 detection of degradation by other means, either 15 tissue where there is compression, stretching of 15 scanning electron microscopy or mechanical testing. 16 the scar tissue, inflammation in the scar tissue, 16 So this is specifically for microscopic appearance 17 17 ischemia, etcetera, wouldn't you? and light microscope. 18 Q. So if you were going to complete 18 A. No. 19 19 the following sentence: "I was the first MR. ORENT: Objection. 20 THE WITNESS: No, I wouldn't agree. 20 pathologist to observe..." what? 21 21 There is no inflammation, there is no edema, scar MR. ORENT: Objection to form. 22 22 THE WITNESS: I don't know if I was tissue doesn't show conditional edema. Scar is 23 pliable, it can change over time. So if there is 23 first one. 24 24 shrinking, it will slowly change because it's BY MS. BYARD: 25 native tissue. 25 Q. You were the first one to report

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Page 194 Page 196 1 findings on degradation of -- degradation bark 1 BY MS. BYARD: 2 under polarized light in microscopic observation? 2 Q. So you could design an experiment 3 MR. ORENT: Objection. 3 where you looked at incidences of exposure, and 4 THE WITNESS: I'm the first one who is 4 whether or not there was curling, and also a 5 describing light microscopy features of 5 control sample where there's curling but not 6 polypropylene degradation. So that would be a full 6 exposure, right? 7 definition. To my knowledge, I am the first one. 7 A. I can tell you for sure, if I see 8 8 BY MS. BYARD: the edge rotated towards, the mesh was curled 9 9 Q. To your knowledge, nobody else has 100 percent. 10 10 done it besides you up until this point? Some cases I see curling completely 11 A. Nobody published. 11 outside of the exposure -- if there's no exposure 12 Q. You continue: 12 surgically described. So, based on these two 13 "From mesh exposure an 13 observations, I can state if curling occurs close 14 14 important finding was that sling to the surface, the edge is prone to be exposed. 15 15 edges rotated or curled towards the Q. You can't say that exposures occur 16 16 at a statistically significant rate with curled surface at the exposure sites." 17 Tell me what you meant by that. 17 mesh edges? 18 THE WITNESS: Sometimes when a reason 18 A. But --19 for excision is mesh exposure, the mesh, if you can 19 Q. Over non-curled mesh edges? 20 see the mesh is rotated -- if this is the mucosal 20 A. What do you compare it with? You 21 surface, I can see it's rotated. I can see the 21 have to -- clinical experiment would be, curled 22 22 curl. If it is a big enough piece and well meshes are placed right under the mucosa, and then 23 oriented then I can see it. 23 the rate of exposure is measured. Can you do that? 24 BY MS. BYARD: 24 You can't. 25 25 Q. Based on your observations to Every time I see it's curled at the Page 195 Page 197 1 date, are you able to say whether the exposure of mucosa, it's exposed; 100 percent, as I said. If 2 the mesh causes the curling or whether the curling 2 it's not at the mucosa, it cannot be exposed 3 causes the exposure? 3 because it's too far. You cannot design experiment 4 4 A. Sometimes it's not curled, but in this retrospective way. 5 5 it's still exposed. So I make a conclusion, Q. Well, there isn't an edge if it's 6 curling which makes it exposed. 6 not exposed though? 7 7 Q. Sometimes it's exposed but not A. No, I don't -- so if you want to 8 8 assess the rate of exposure, which would occur due curling, though, right? 9 A. Yes. 9 to curling, you would have to place flat meshes 10 10 Q. Okay. So something other than the under the surface and then curled meshes under the 11 curling causes the exposure in those instances? 11 surface, observe them for five, six years, and then 12 A. There might be different 12 calculate the rate. That would be start answering 13 mechanisms, but one of the mechanisms is curling. 13 14 14 Q. Okay. Right now what I see, if it's curled 15 A. Most of the curled part is inside 15 and it's at mucosa, it's 100 percent exposed. But 16 the exposure site. It's only the tip which is 16 as I said, sometimes it's flat and it's still 17 exposed. 17 exposed. Or, in orientation I cannot assess if 18 18 Q. And you haven't done a statistical it's curled, not curled. It's just poor 19 19 analysis in order to say whether or not this edge orientations. 20 20 curling phenomena occurs with a statistically -- at Q. You conclude with a message: 21 a statistically significant rate with exposures to 21 "Polypropylene degradation 22 22 conclude there's a causal relationship, right? needs to be studied further for its 23 MR. ORENT: Objection. 23 role in inflammation, mesh hardening 24 THE WITNESS: I don't understand what 24 and late deformation, as well as for 25 would you compare with -- I mean, what -- I mean --25 the properties of chemical

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	Page 198		Page 200
1	degradation products."	1	consulting in Exhibit 1199, right?
2	Did I read that correctly?	2	A. Well, this is
3	A. That is correct.	3	MR. ORENT: Objection.
4	Q. And here again, what this	4	THE WITNESS: clearly disclosed.
5	conclusion reinforces, is that there's a need for a	5	BY MS. BYARD:
6	further study to understand the details of the	6	Q. Where?
7	mechanisms of actions of the relationships between	7	A. "Some external consultations sent
8	degradation and inflammation, as well as mesh	8	for litigation purposes" see, again, this was a
9	hardening, and whether any chemical degradation	9	very structured way of submitting abstract. I
10	products are produced or what they are, right?	10	didn't have much flexibility to put in. I had a
11	MR. ORENT: Objection.	11	drop-down menu for funding only.
12	THE WITNESS: That's correct. Because	12	See if it's see, funding, subject,
13	what we know? We know that some patients present	13	ethics committee and everything else, I could enter
14	with complaints six or eight years after the	14	only specific amount of information in the
15	insertion.	15	drop-down menu. So I tried my best to disclose as
16	So the only thing which changes over	16	much as I can.
17	time is the degree of degradation. So degradation	17	Q. So your testimony is that for
18	layer or bark is getting thicker, so it's inflamed	18	1198 and 1199, there was a free text field you
19	and so forth.	19	could type in?
20	So from what we know now, the only late	20	MR. ORENT: Objection.
21	factor which happens around the mesh or to the mesh	21	THE WITNESS: To a certain degree I
22	is degradation. So those changes which occur later	22	don't remember exactly now but I mean it was
23	on, will have more larger component of	23	which one?
24	degradation within the mechanisms of this.	24	BY MS. BYARD:
25	But how exactly it occurs, then again,	25	Q. The one we looked at before where
		25	`
-	Page 199		Page 201
1	it needs to be studied. Or, if I observe a bark or	1	you published with Dr. Carey?
2	degradation layer, I can see the cracks in it. I	2	A. This one was free text, just
3	know that they're internal forces which shrink it.	3	submitted paper. It was just, um, paragraph
4	But how much of that, how all these forces work, I	4	disclosures, this one was more restricted.
5	mean, it all needs to be studied.		
6		5	Q. And so but you typed in the
	BY MS. BYARD:	6	words, "Some specimens were received as external
7	Q. You also write here one sentence	6 7	words, "Some specimens were received as external consultations sent for litigation purposes."
7 8	Q. You also write here one sentence before this:	6 7 8	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it.
7 8 9	Q. You also write here one sentence before this:  "The compartmentalizing nature	6 7 8 9	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it.  Q. And again, the word "for
7 8 9 10	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth	6 7 8 9	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it?
7 8 9 10 11	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the	6 7 8 9 10 11	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed
7 8 9 10 11 12	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms."	6 7 8 9 10 11 12	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it?  A. No. But, as I said, we discussed it before.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms."  Do you see that? It's just one sentence before the one we just read.  A. Can you point on your copy?  Q. Yes, here.  A. Yes, that's correct.  Q. Again, you've used this word "may"?  A. Again, because all these  Q. That's my only question. That's	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed it before.  MS. BYARD: We need to take a break now for everyone.  THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so.  MS. BYARD: Do you mind if we discuss this off the record?  MR. ORENT: Yes, sure.  THE VIDEOGRAPHER: Going off the record
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms."  Do you see that? It's just one sentence before the one we just read.  A. Can you point on your copy?  Q. Yes, here.  A. Yes, that's correct.  Q. Again, you've used this word "may"?  A. Again, because all these Q. That's my only question. That's the word that you've used, right?  A. Well, it's written.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed it before.  MS. BYARD: We need to take a break now for everyone.  THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so.  MS. BYARD: Do you mind if we discuss this off the record?  MR. ORENT: Yes, sure.  THE VIDEOGRAPHER: Going off the record at 1:40 p.m.  RECESS AT 1:40 p.m.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You also write here one sentence before this:  "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms."  Do you see that? It's just one sentence before the one we just read.  A. Can you point on your copy?  Q. Yes, here.  A. Yes, that's correct.  Q. Again, you've used this word "may"?  A. Again, because all these  Q. That's my only question. That's the word that you've used, right?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	words, "Some specimens were received as external consultations sent for litigation purposes."  A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed it before.  MS. BYARD: We need to take a break now for everyone.  THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so.  MS. BYARD: Do you mind if we discuss this off the record?  MR. ORENT: Yes, sure.  THE VIDEOGRAPHER: Going off the record at 1:40 p.m.

51 (Pages 198 to 201)

	Page 202		Page 204
1	record at 2:16 p.m.	1	My question for you is whether this 130
2	BY MS. BYARD:	2	meshes includes Gore-Tex and combined designs in
3	Q. Doctor, I'm handing you	3	addition to polypropylene mesh?
4	Exhibit 1200. I'll ask if you recognize that?	4	A. No. This would just be POP and
5	A. Yes, I do.	5	knitted polypropylene meshes.
6	Q. This was an abstract that you	6	Q. And then you describe here some
7	published this year with the let me start over.	7	findings that we've already discussed in
8	This was an abstract that was published this year?	8	relationship to your other article with Dr. Carey,
9	A. Yes, that's correct.	9	correct?
10	Q. The title is, "Explanted Surgical	10	A. That's correct.
11	Meshes: What Pathologists and Industry Failed to	11	Q. Are there any findings reported
12	Do for Over 50 Years"; is that right?	12	here that are different, or in addition to the
13	A. For 50 years.	13	findings reported in the full length article that
14	Q. Thank you. Under "Objective" you	14	you authored with Dr. Carey and Dr. Steege?
15	write, three sentences in:	15	A. Um, this was a smaller abstract
16	"Estimated millions of devices	16	which, as you can see, combine transvaginal meshes,
17	have been excised over the years,	17	slings and POP devices and hernia meshes. So this
18	however, the study material remain	18	is more of a descriptive study of all meshes,
19	largely ignored and the mechanisms	19	irrespective of their anatomical location. Where
20	of complications are still poorly	20	other papers were concentrated on specific type of
21	understood".	21	transvaginal locations, whether slings or POP devices.
22	A. That's correct.	22	Q. And so it wouldn't be true to say
23	Q. Under "method" you write:	23	that the 120 specimens that you described in your
24	"130 meshes excised from	24	litigation report are all included in this
25	different anatomical sites were	25	abstract, correct?
	Page 203		
			Dage 2051
-			Page 205
1	studied in search of features	1	A. You see the abstract was written
2	studied in search of features explaining the complications."	2	A. You see the abstract was written earlier, a few months earlier so
2	studied in search of features explaining the complications."  Did I read that correctly?	2	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130
2 3 4	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct.	2 3 4	A. You see the abstract was written earlier, a few months earlier so Q. The reason why we get to 130 specimens is because you've included other types of
2 3 4 5	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD:	2 3 4 5	A. You see the abstract was written earlier, a few months earlier so Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh,
2 3 4 5 6	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens	2 3 4 5 6	A. You see the abstract was written earlier, a few months earlier so Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?
2 3 4 5 6 7	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh?	2 3 4 5 6 7	A. You see the abstract was written earlier, a few months earlier so Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was
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2 3 4 5 6 7 8 9 10 11 12 13	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight,	2 3 4 5 6 7 8 9 10 11 12	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number,
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.  Q. Okay. So including sources of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.  Q. Okay. So including sources of specimens from provided to you from Plaintiffs'
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.  Q. Okay. So including sources of specimens from provided to you from Plaintiffs' counsel in the mesh litigation?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that you've examined include slings and POP devices,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.  Q. Okay. So including sources of specimens from provided to you from Plaintiffs' counsel in the mesh litigation?  MR. ORENT: Objection.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	studied in search of features explaining the complications." Did I read that correctly? THE WITNESS: That's correct. BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. You see the abstract was written earlier, a few months earlier so  Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?  A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.  Q. Can you tell me how many of these 130 specimens were transvaginal mesh?  A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this  Q. Okay.  A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.  Q. Okay. So including sources of specimens from provided to you from Plaintiffs' counsel in the mesh litigation?

52 (Pages 202 to 205)

1 A. There was 97, yes. 2 Q. You conclude that: 3 "General lack of interest created a paradoxical gap of 4 bundant study material and readily available tools." 5 knowledge in the presence of abundant study material and readily available tools." 7 Right. 8 Right. 8 Right. 8 Right. 9 A. That's correct. 9 Page 207 1 published. 1 It his I gave disclosure in Exhibit 1200, right? 2 Page 207 2 Pages A. On the paper, no. 8 Pages are in Exhibit 1200, is there? A. On the paper, no. 10 Q. There is no confluct of interest dappears here in Exhibit 1200, is there? A. On the paper, no. 10 Q. There is no con Plaintiff's 'do row and Plaint	
2 Q. You conclude that: 3 "General lack of interest 4 created a paradoxical gap of 5 knowledge in the presence of 6 abundant study material and readily 7 available tools."  8 Right. 9 A. That's correct. 10 Q. You continue: 11 "The newly described findings need to be studied in correlation 12 with clinical symptoms to guide 14 future developments." 15 Correct? 16 THE WITNESS: That's correct. 17 BY MS. BYARD: 20 The title of title of title of this abstract is: 16 THE WITNESS: That's correct. 17 BY MS. BYARD: 20 Christidy doesn't describe any correlation of your histological findings with clinical symptoms, does it? 21 A. No, not directly. 22 Q. There is no conflict of interest disclosure in Exhibit 1200, right? 24 A. It was provided later in the presentation, I believe. It's just the way it was  Page 207  1 published. 2 I think I gave disclosures during submission. But the way they publish it, there's no oidsclosure. I can see there's no other disclosures for any other abstracts. 4 C. There's not a disclosure that appears here in Exhibit 1200, is there? 4 A. On the paper, no. 2 Overlooked for Decades," br. S. Guelcher, Dr. R. Bendavid. BY MS. BYARD: Q. Exhibit 1201 will be passed to you here momentarily. MR. ORENT: This is 1201 you said? A. Yes. That's the same conference, the same submission process. The same journal same issue.  10 Q. The title of tibs abstract is: 11 "In vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades." A. That's correct. BY MS. BYARD:  10 Q. And this is published with Dr. Scott Guelcher and Dr. Bendavid, right?  11 MR. ORENT: This is 1201 you said?  12 A. Yes. That's the same conference, the same submission process. The same journal same issue.  13 In vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades."  14 A. That's correct.  15 Q. And this is published with Dr. Scott Guelcher and Dr. Bendavid, right?  16 MR. ORENT: Guelche	
3	
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Right.  Right.	., the
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8 A. On the paper, no. 8 involved together, yes, he was on Plaintiffs' side	
9 MR. ORENT: Objection. 9 Could have been on manufacturer side for some	e.
	ething
10 THE WITNESS: But it doesn't mean that 10 else.	-
11 it was not provided, or was not disclosed elsewhere   11 Q. But as far as you know, it's been	
12 assuming for presentation. 12 on the Plaintiffs' side, right?	
13 If it's a presentation, I give slide 13 MR. ORENT: Objection.	
with some disclosure, which is usually first slide 14 THE WITNESS: I don't make the	
15 before the presentation. 15 distinction. Because as I said, I mean, this is up	
16 BY MS. BYARD: 16 to me to decide, or any other reader if there is a	,
Q. Okay. If you're able to find the 17 bias on which side and how it is presented.	
18 disclosure form that you think you might have 18 BY MS. BYARD:	
19 completed for this, would you provide it to counsel   19 Q. My only question is, as far as you	
20 for me? 20 know, he served as a testifying expert for	
A. I could not have it, because it 21 Plaintiffs against mesh manufacturers, correct?	
22 was electronic submission. 22 A. That's correct.	
Q. Okay. 23 Q. Under "Objectives", you write:	
EXHIBIT NO. 1201: Abstract entitled, 24 "Surgical polypropylene meshes	
25 "In-vivo Degradation of Surgical 25 introduced over 50 years ago are	

53 (Pages 206 to 209)

	Page 210		Page 212
1	excised in up to 10 percent for	1	A. Yes.
2	complications."	2	Q. That study has not yet been
3	Did I read that correctly?	3	completed, true?
4	A. Yes.	4	A. What exactly? Which study?
5	Q. Is this a statistic for hernia	5	Q. The study of the role of
6	mesh or for transvaginal mesh?	6	degradation in the development of complications?
7	A. This is difficult now to remember.	7	A. It doesn't state it there as a
8	Because it was based on all of those. So "up to"	8	study.
9	means the highest number I could see in	9	Q. You write:
10	sufficiently reliable source.	10	"The discovery opens the door
11	Q. Sometimes the rate is lower than	11	to study the role of degradation in
12	that in the reported literature, true?	12	the development of complications".
13	A. It's a range. I mean, if you take	13	A. Yes. But it doesn't state that we
14	small sample size, one single mesh which has not	14	have a study ongoing to do that. "Study" is used
15	been excised, you don't have any rate. If a sample	15	as a verb here not as a noun.
16	size goes larger, then you get more or less	16	Q. You haven't yet published anything
17	representative sample of the whole population.	17	on the role of degradation and the development of
18	Q. For this statement, were you	18	complications, right?
19	including literature on rates of removal from both	19	A. On exact mechanisms? No.
20	hernia repair and transvaginal mesh repairs?	20	Q. There is no conflict of interest
21	A. It was pertinent to both. So I	21	disclosure in Exhibit 1201 for you, is there?
22	don't remember exactly if 10 percent was for hernia	22	MR. ORENT: Objection. Asked and
23	or transvaginal. I suspect it could have been for	23	answered.
24	transvaginal from what I remember.	24	THE WITNESS: The same thing. During
25	Q. You write:	25	submission there was an option, if there was an
	Page 211		Page 213
1			
1	"We studied 103 explanted	1	option, submitted all information I could during
2	meshes and different designs,	2	presentations. If it's PowerPoint presentation,
3	manufacturers and anatomical sites	3	the first slide which appears after the title slide
4	using conventional and transmission	4	is disclosure of conflict.
5	electron microscopy."	5	BY MS. BYARD:
6	Correct?	6	Q. A conflict of interest disclosure
7	A. That's correct.	7	does not appear in Exhibit 1201, does it?
8	Q. Why are we at 103 here, compared	8	MR. ORENT: Objection.
9	to the sample size of 120 we saw in Exhibit 1200?	9	THE WITNESS: It's up to a journal.
10	A. Multiple reasons. It could be	10	BY MS. BYARD:
11	different point in time when this abstract was	11	Q. Is there a conflict of interest
12	written. Something else, like not completed study	12	disclosure that appears in Exhibit 1201, sir?
13	at that time, because I would need polarize or	13	MR. ORENT: Objection.
14	measure the degradation thickness; so I don't know.	14	THE WITNESS: I don't see it.
15	But at that time when the abstract was written,	15	Maybe it was somewhere at the end of
16	total number was 103.	16	the journal issue, I don't know. I mean, this is
17	Q. You conclude this abstract by	17	just a page from the issue. Maybe they had
18 19	writing:	18	conflict of interest gathered at the end.
20	"The discovery" and you're	19	BY MS. BYARD:
	referring to the discovery of	20	Q. I'd like to turn back to your
21	degradation under microscopy	21 22	report, which is Exhibit 1196.  Are you on the "Opinion" section with
$\gamma \gamma$			Are you on the Uninion Section With
22	" opens the door to study the role		
23	of degradation in the development of	23	me, sir?
	- · · · · · · · · · · · · · · · · · · ·		

54 (Pages 210 to 213)

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Page 214
                                                                                                       Page 216
 1
                 "Explanted mesh specimens show
                                                            1
                                                                        A. Yes. They are important to
 2
              non-specific reaction of the body to
                                                            2
                                                                 understand. I mean, everything is important to my
                                                            3
 3
              a foreign object, as well as findings
                                                                 opinion, because I wouldn't be providing this
              specific for a mesh type or an
                                                            4
                                                                 opinion if I didn't go to medical school. So you
 4
                                                            5
 5
              anatomical location."
                                                                 have to go back to 1986.
                                                            6
                                                                        Q. I don't think we have time for
 6
              Is that right?
                                                            7
 7
              A. That's correct.
                                                                 that, unfortunately.
                                                            8
 8
                                                                        Under paragraph 2 of your opinions,
              O. You continue:
 9
                  "Findings for abdominal mesh
                                                            9
                                                                 there's a sentence that reads:
10
              explants differ from findings for
                                                          10
                                                                           "This reaction --" and you're
11
              vaginal mesh implants."
                                                          11
                                                                        talking about the foreign body
12
              A. That's correct.
                                                          12
                                                                        reaction "-- persists until the
13
              Q. How so?
                                                          13
                                                                        inciting agent is either removed, in
14
              A. I've explained some of the
                                                          14
                                                                        parenthesis, [expelled or reabsorbed]."
15
                                                          15
                                                                        Are you with me?
      differences earlier. Hernia meshes are placed in
16
                                                          16
                                                                        A. "Resorbed".
      parallel to anatomical planes. There are
17
      separated, well defined planes between fascia,
                                                          17
                                                                        Q. Resorbed. Thank you.
18
      adipose tissue, muscle and transvaginal
                                                          18
                                                                        Does there come a point in time, in the
19
      allocations. There is no fascia, really, there's
                                                          19
                                                                 tissue response to mesh, where the inflammatory
20
      no anatomical plane. The tissue gradually
                                                          20
                                                                 response reaches a chronic or steady state?
21
      transitions into -- one to another.
                                                          21
                                                                        A. Foreign body reaction is a chronic
22
                                                          22
                                                                 inflammatory reaction.
              Another difference is that functionally.
23
      abdominal wall is just holding pressure of --
                                                          23
                                                                        When it starts, it may start acutely
24
      abdominal pressure. While vaginal tissue has
                                                          24
                                                                 but on its own it's a chronic response. Not may
25
      completely different purpose. There is more
                                                          25
                                                                 start; it starts acutely after the placement of
                                            Page 215
                                                                                                       Page 217
 1
      mobility, there is stress of bladder expansion,
                                                            1
                                                                 foreign body, and then continues on as a chronic
 2
      bowel movement, then stress of intercourse.
                                                            2
                                                                 response.
 3
             Muscles within the bladder wall,
                                                            3
                                                                        Q. Does the foreign body response
 4
      muscles within the vaginal wall which contract,
                                                            4
                                                                 drop off over time?
                                                            5
 5
      type of innervation is completely different.
                                                                        A. Not in what I see. In relation to
 6
             Where in the abdominal wall, it mainly
                                                            6
                                                                 polypropylene, I see even -- I think my oldest
                                                            7
 7
      serves as a passage of nerves parallel to abdominal
                                                                 specimen was 12 years after insertion, and I still
                                                            8
 8
      wall, where the vagina is practically the target of
                                                                 see inflammatory -- chronic body -- chronic foreign
      innervation, because the endings are there, and the
                                                            9
                                                                 body type reaction.
 9
10
                                                          10
      nerves are in different orientation.
                                                                        So in relation to polypropylene, it's a
                                                                 variable. But I've never seen it went away
                                                          11
11
             And I can continue on and on, I mean
12
                                                          12
      it's -- abdominal wall is a completely sealed
                                                                 completely.
13
      environment, there's no contamination. Vaginal
                                                          13
                                                                        Q. Does the foreign body reaction
14
      environment is contaminated. Do you want me to
                                                          14
                                                                 drop off after this acute phase that you've
15
      continue?
                                                          15
                                                                 described? And I don't mean completely, but just
16
             Q. Are those the main differences
                                                          16
                                                                 decrease?
                                                          17
17
      that you're noting?
                                                                        A. That was one of the questions.
18
             A. I mean --
                                                          18
                                                                 And I would expect that it would decrease, but so
                                                          19
19
             Q. Those are the ones that are
                                                                 far have not been able to show it. Every time I'm
      important to your opinions here?
                                                          20
                                                                 checking, every time data builds up and then I
20
21
              A. I can continue more with the
                                                          21
                                                                 check if there is correlation between foreign body
22
                                                          22
      differences.
                                                                 reaction, what degree, and I'm just -- it doesn't
23
             Q. Are they relevant to your opinions
                                                          23
                                                                 correlate vet.
      in this report, the other differences besides those
24
                                                          24
                                                                        Maybe I need to go to a thousand cases
25
      that you've mentioned?
                                                                 and then I see some weak correlation. What seems
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55 (Pages 214 to 217)

	Page 218		Page 220
1	to be a case that it's variable between	1	that was. I mean, I just don't remember now.
2	individuals, or maybe it's variable within the same	2	Q. Okay. And that's fine. And I
3	individual, so it fluctuates with time. But again,	3	think your testimony in response to my question
4	that's why we need to study all this.	4	about how many sutures are placed, for example,
5	Q. So those conclusions haven't been	5	during abdominal paravaginal repair, is that you
6		6	don't know for certain that the amount of materials
7	established yet, based on your observations to date?	7	are less than with the surgical mesh; is that fair?
8		8	
	MR. ORENT: Objection.	1	A. Significantly less, that is fair.
9	THE WITNESS: What exactly defines the	9	Q. You write in paragraph 4 of your
10	degree of foreign body reaction? No, the degree is	10	opinions, and I'm just reading part of the sentence
11	not.	11	that I want to ask you about is that:
12	I mean, we know	12	"The filaments" here you're
13	BY MS. BYARD:	13	referring to vaginal mesh " are
14	Q. The degree and I guess what I'm	14	always surrounded by fibrous scar."
15	focusing on is, it's activity over time?	15	Do you see that?
16	A. Yes. This is not completely	16	A. Yes.
17	understood. What we know, it is present and it is	17	Q. Is it true that you see tissue
18	always present.	18	changes to mesh adjacent to the mesh, but at some
19	Q. Okay.	19	point you see a resumption in normal tissue
20	A. In all specimens.	20	response?
21	Q. You write here in your third	21	A. What do you mean, "resumption of
22	paragraph that:	22	normal tissue response?"
23	"A mesh is a large foreign body	23	Q. So you see a foreign body reaction
24	in comparison to regular surgical	24	and chronic inflammatory state in the tissue
25	sutures." Right?	25	immediately adjacent to the mesh, correct?
	Page 219		
	Page 219		Page 221
1	A. That's correct.	1	A. That's correct.
1 2	A. That's correct.	1 2	A. That's correct.
	<ul><li>A. That's correct.</li><li>Q. Do you note how many surgical</li></ul>	1	<ul><li>A. That's correct.</li><li>Q. But at some point and distance</li></ul>
2	<ul><li>A. That's correct.</li><li>Q. Do you note how many surgical sutures are used, for example, in abdominal</li></ul>	2	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to
2	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs?	2	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct?
2 3 4	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every	2 3 4	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue
2 3 4 5	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller	2 3 4 5	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct?
2 3 4 5 6	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be.	2 3 4 5 6	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal.
2 3 4 5 6 7	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance	2 3 4 5 6 7	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond;
2 3 4 5 6 7 8	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair?	2 3 4 5 6 7 8	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the during the surgery. There's	2 3 4 5 6 7 8 9 10 11 12 13 14	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the during the surgery. There's no need for that. Q. My question to you, sir, was whether you've ever seen an abdominal paravaginal repair performed; and I think your testimony is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already. BY MS. BYARD: Q. Okay, thank you for that correction. There's an edge that you see away from
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the during the surgery. There's no need for that. Q. My question to you, sir, was whether you've ever seen an abdominal paravaginal repair performed; and I think your testimony is that you can't say for certain you have seen	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already. BY MS. BYARD: Q. Okay, thank you for that correction. There's an edge that you see away from the mesh, where there's a resumption in normal
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the during the surgery. There's no need for that. Q. My question to you, sir, was whether you've ever seen an abdominal paravaginal repair performed; and I think your testimony is that you can't say for certain you have seen abdominal pelvic surgeries performed?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already. BY MS. BYARD: Q. Okay, thank you for that correction. There's an edge that you see away from the mesh, where there's a resumption in normal tissue?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say. In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the during the surgery. There's no need for that. Q. My question to you, sir, was whether you've ever seen an abdominal paravaginal repair performed; and I think your testimony is that you can't say for certain you have seen	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can THE WITNESS: there is an edge MR. ORENT: Hold on. Slow down and let him answer. THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already. BY MS. BYARD: Q. Okay, thank you for that correction. There's an edge that you see away from the mesh, where there's a resumption in normal

56 (Pages 218 to 221)

	Page 222		Page 224
1	Q. Have you measured to find a range	1	THE WITNESS: Thank you.
2	at which the average return to normal tissue is	2	THE VIDEOGRAPHER: Off the record at
3	from the mesh?	3	2:44 p.m.
4	A. I don't think you're using words	4	RECESS AT 2:44
5	"return" is not	5	UPON RESUMING AT 4:35
6	Q. Okay.	6	THE VIDEOGRAPHER: We're back on the
7	A. It's not applicable. You don't	7	record at 4:37 p.m.
8	know if it was scar and then return actually,	8	BY MS. BYARD:
9	it's impossible.	9	Q. Doctor, attached to your report
10	Q. Okay. So is there, I guess and	10	are a number of figures numbered 1 through 20,
11	help me with how to phrase it. But is there a	11	correct?
12	distance have you measured let's start over.	12	A. Figure sets, I believe, sometimes
13	Have you measured how far away from the	13	they are gathered in sets.
14	mesh the tissue ordinarily appears normal?	14	Q. Sitting here today, is it true
15	A. Yes. I didn't perform statistical	15	that you are not able to tell me what clinical
16	analysis or study, but I measured approximately	16	complications or symptoms led to each of these
17	what's the distance of changes.	17	patients whose specimens are depicted in Figures 1
18	Q. And what is that distance on	18	through 20? Wait, let me start over, I don't think
19	average?	19	I finished that right. Strike that.
20	A. It's within one to two millimeters,	20	Now, is it true that sitting here
21	not greater than two, at least from most of the	21	today, you're not able to tell me that clinical
22	cases I see.	22	symptoms leading to these excision surgeries of
23	Q. So in most instances, when looking	23	each of the patients whose specimens are depicted
24	at a transvaginal mesh and tissue specimen, you	24	in Figures 1 through 20?
25	will see normal tissue one to two millimeters from	25	A. You mean, do I remember the
23			71. Tou mean, do i temember the
	Daga 222		Dago 225
1	Page 223	1	Page 225
1	the mesh?	1	history for a specific photograph and
2	the mesh? A. Yeah. From the most, outermost	2	history for a specific photograph and Q. (Nods).
2	the mesh?  A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to	2 3	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant?
2 3 4	the mesh?  A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two or I would say, to be safe, one to three	2 3 4	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant? Q. Yes, that was what I meant. Thank
2 3 4 5	the mesh?  A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two or I would say, to be safe, one to three millimeters. I don't see it exceeding three	2 3 4 5	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant? Q. Yes, that was what I meant. Thank you.
2 3 4 5 6	the mesh?  A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two or I would say, to be safe, one to three millimeters. I don't see it exceeding three millimeters, unless there is something else, like	2 3 4 5 6	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant? Q. Yes, that was what I meant. Thank you. A. I don't remember histories, I
2 3 4 5 6 7	A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two or I would say, to be safe, one to three millimeters. I don't see it exceeding three millimeters, unless there is something else, like an abscess.	2 3 4 5 6 7	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant? Q. Yes, that was what I meant. Thank you. A. I don't remember histories, I mean, they are all collected from Boston Scientific
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two or I would say, to be safe, one to three millimeters. I don't see it exceeding three millimeters, unless there is something else, like an abscess.  If there's an abscess, then there is much more scarring in the area. Or, if there is erosion, there's inflammation, there is much more damage to the tissue, then it expands.  But if we go into deep environment and changes which can be only attributed to mesh, then it's within three millimeters beyond the mesh.  But, if the mesh is curled, or folded like POP, the distance between two mesh planes in the fold can be much greater, five, six millimeters, and this will all be filled by scar. I'm talking about extent towards normal tissue.  Q. That's what I was asking.  A. Externally, yes.  Q. Okay. Good.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	history for a specific photograph and Q. (Nods). A. I don't. Is it what you meant? Q. Yes, that was what I meant. Thank you. A. I don't remember histories, I mean, they are all collected from Boston Scientific or most of them. If it's not, they are specified to be a known Boston Scientific. Q. Okay. And so similarly, you aren't able to tell me that for the figures numbered 1 through 20, when any symptoms began, that led to the excisions resulting in the specimens whose that are depicted in Figures 1 through 20, right? MR. ORENT: Objection. THE WITNESS: When specific symptoms began?  BY MS. BYARD: Q. (Nods.) A. No, I cannot. Q. Okay. Thank you, Doctor.

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	Page 226		Page 228
1	A. Yes.	1	ahead.
2	Q. I just want to look at one	2	THE WITNESS: We have to kind of
3	sentence there at the end, where you write that:	3	separate it, other clinical publications saying
4	""Mature scar tissue after	4	that mesh non-mesh surgeries are free of
5	non-mesh surgeries"the sentence	5	complications?
6	continues " can remodel with time."	6	No. Because any surgery has a form of
7	Can you see that?	7	complication early complications, or later
8	A. Yes, I do.	8	complications. I mean, it depends what surgery. I
9	Q. Is it your opinion that scar	9	mean, then again, it's so broad and kind of worded
10	tissue from mesh surgeries can't remodel with time?	10	in
11	A. Cannot or can?	11	BY MS. BYARD:
12	Q. Cannot.	12	Q. Okay, sure. And I just wanted to
13	A. It can. It can remodel, but the	13	see if we could agree that non-mesh surgeries can
14	mesh cannot remodel.	14	also result in long-term clinical complications?
15	Q. So the scar tissue I'm sorry.	15	MR. ORENT: Objection.
16	A. So there will always be scar	16	THE WITNESS: Which I mean, any
17	around the mesh. If mesh travels, migrates, the	17	surgery will have specific complications. Early or
18	scar will remodel.	18	later, we have to take specific surgery and then
19	So does that answer your question?	19	compare. Non-mesh surgery will not have long-term
20	Q. Yes, it does.	20	complications of meshes; that's clear.
21	So you would agree with me that scar	21	If there is no mesh, there will not be
22	tissue surrounding mesh can remodel over time?	22	complications related to the mesh. If there is
23	A. Yes, it can.	23	mesh, there can be complications related to the
24	Q. Okay. The sentence continues that:	24	mesh.
25	"Mature scar tissue from	25	mesi.
	Page 227		Page 229
1	non-mesh surgeries does not exhibit	1	BY MS. BYARD:
2	the same long-term reactions or	2	Q. So you can't cite for me, can you,
3	clinical complications".	3	what the rate of pain with a non-mesh
4	Do you see that?	4	perineorrhaphy is compared to a posterior repair
5	A. That's correct.	5	with mesh; can you?
6	Q. I just want to focus on the term	6	MR. ORENT: Objection. Outside the
7	"clinical complications" with you, okay?	7	scope.
8	Would you agree with me that there is	8	THE WITNESS: I'm not a clinician, so
9	no peer-reviewed published literature concluding	9	you have to ask other expert this question.
10	that non-mesh surgical procedures are free of	10	BY MS. BYARD:
11	long-term clinical complications?	11	Q. Okay, thank you.
12	MR. ORENT: Can you read that back?	12	Your next paragraph, paragraph 6, deals
13	I'm sorry.	13	with your opinions related to degradation, right?
14	THE WITNESS: I'm confused as well,	14	A. That's correct. Let me see.
15	yeah.	15	(Witness reviews document).
16	REPORTER'S NOTE: Whereupon the	16	Yes, that's correct.
17	question was read back as follows:	17	Q. As I understand it, there are
18	"Would you agree with me that	18	three principle findings from which you conclude
19	there is no peer-reviewed published	19	that polypropylene mesh degrades in vivo, all
1 1 2		1	
	-	20	right?
20	literature concluding that non-mesh	20	right?  First you opine that the ability of the
20 21	literature concluding that non-mesh surgical procedures are free of	21	First you opine that the ability of the
20 21 22	literature concluding that non-mesh surgical procedures are free of long-term clinical complications?"	21 22	First you opine that the ability of the non I'm sorry, let me start over.
20 21 22 23	literature concluding that non-mesh surgical procedures are free of long-term clinical complications?" THE WITNESS: You can state it for any	21 22 23	First you opine that the ability of the non I'm sorry, let me start over. First, you describe that the ability of
20 21 22	literature concluding that non-mesh surgical procedures are free of long-term clinical complications?"	21 22	First you opine that the ability of the non I'm sorry, let me start over.

58 (Pages 226 to 229)

Page 230 Page 232 1 A. No, this is not correct. You're 1 that it's polypropylene. So these would be 2 mixing up things. So let's split it. 2 findings in light microscope. And if we go to 3 3 If you want me to explain, I will transmission electron microscopy, I can see 4 explain. If you want me to answer your question, I 4 transition. I see non-degraded, sort of finely 5 will; what do you want? granule, almost smooth, no granulation, sort of 6 Q. Okay. Well, you have three -- you 6 granularity. And then there's a smooth transition 7 have three basic findings. 7 into smaller cracks, fine lattice of cracks, and 8 8 A. No, no, not three. There are way then it expands, and expands, and expands in larger 9 9 more than three, but... crevices towards the surface. 10 10 MR. ORENT: Just let her --So there's a range of degradation from 11 THE WITNESS: Okay. 11 a core to the surface. So this findings would 12 BY MS. BYARD: 12 confirm that this is -- this stainable layer is in 13 Q. Is it your opinion that 13 fact polypropylene. 14 14 polypropylene mesh degrades in vivo, in part Q. Okay. So then what was wrong with 15 because the degraded bark is able to trap 15 my question --16 histological dyes? 16 MR. ORENT: Wait, hold on. He's not 17 A. No, this is not correct. 17 done. 18 Q. Explain it to me then. 18 THE WITNESS: Then there's a next set 19 19 A. So let's dissect it. of findings, which is proving that it is altered or 20 So first, what findings in the light 20 degraded polypropylene. 21 microscope and electron transmission microscope 21 All right. First, we concluded that it 22 22 through cross-sections prove that the layer I is polypropylene. And the second set of findings 23 observe is polypropylene? 23 proving that it's altered polypropylene. 24 So the first finding, light microscopy, 24 Obviously, first thing which is visible 25 it polarizes. So it behaves as polypropylene --25 in light microscopy is it observes dye. Page 231 Page 233 1 non-degraded polypropylene in polarized light. So 1 Non-degraded polypropylene is completely clear, 2 this is first finding. 2 it's solid, it doesn't have pores to trap dyes. 3 Second finding is that those mesh 3 The degraded polypropylene absorbs 4 filaments where there are blue granules included, I dyes. And, if I do staining with two stains, one 5 observed them in this stainable layer. So this is is with small molecular size of the dye, and one is 6 another proof that it's coming from polypropylene. 6 larger molecular size of the dye. The smaller 7 Then with other stains, as for one 7 molecule -- the dye with smaller molecule size will 8 8 cause of stain, because the stainable layer is retain in smaller cracks, really fine sort of brittle, it cracks. So the first question for 9 microcracks. And then larger molecules would stay 9 pathologists would be, can it be calcified 10 10 in the larger. material? Which is very common to have calcified 11 11 So, therefore, I had this trichrome 12 material in human body, especially with long-term 12 stain layer of red, which indicates smaller 13 13 chronic processes. So I did Von Kossa stain, porosity we see in the degraded material, and then 14 calcium stain, it's not -- it's not staining for 14 a layer of green color, which highlights a larger 15 calcium. 15 porosity material. So this is degraded in light 16 The next set of stains was to stain for 16 microscopy. 17 proteins, because if it's a protein, it mixes, it's 17 Cracking, that's another feature. Peeling off. So what happens, there is internal 18 a hydrophilic mix of some sort, to mix with 18 19 19 proteins. So I stained it for several force -- it's like drying, it's like drying on lips 20 ubiquitous -- "ubiquitous" means present in many 20 or like rust on the surface of the metal. Because 21 body fluids, immunoglobins, and it doesn't stain 21 it shrinks somewhat, and then the internal force 22 22 the layer. It's deposited right next to it, it pulls it, there's a crack, but it pulls and sloughs 23 goes into crevices, it follows the surface, but it 23 off of non-degraded surface, and then it starts 24 24 doesn't mix. Again, this shows that the material peeling.

59 (Pages 230 to 233)

So that's another feature showing that

25

25

is hydrophobic, and doesn't mix again; proof is

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Page 234
                                                                                                         Page 236
 1
      it's degrading, it's changing properties, physical
                                                             1
                                                                  because it's dead then, they get stuck. So this is
 2
      properties and it's non-degraded material.
                                                             2
                                                                  another process. Degraded material was present in
 3
             BY MS. BYARD:
                                                             3
                                                                  vivo, while the inflammatory cells were mobile, so
 4
                                                             4
                                                                  they could do that. So that's kind of overview.
             Q. Okay.
                                                             5
 5
             A. And then there is a third set of
                                                                          O. And maybe we're talking past each
 6
                                                             6
      findings, which proves that it happens in vivo. So
                                                                  other. What I was focusing on was paragraph 6.
 7
      "in vivo" means that it happens before it is --
                                                             7
                                                                  And there you list its ability to trap histological
                                                             8
 8
             Q. Explanted?
                                                                  dyes, right?
                                                             9
 9
             A. Piece of mesh is excised. So one
                                                                          A. That's proof that it's altered.
10
                                                            10
      of the findings is that some surgeries are done
                                                                          Q. There you also list that it
11
      with electric cautery devices. So the edges of the
                                                            11
                                                                  retains inclusions of blue granules?
12
      specimen are burned, and it melts polypropylene.
                                                            12
                                                                          A. That's proof that it was protein,
13
      So this sides, I can see that the degraded material
                                                            13
                                                                  that it's originating from original protein. Not
14
      melted, and non-degraded material melted. And then
                                                           14
                                                                  protein, I'm sorry. Polypropylene. That it
15
      they melt together and form one pool, and they
                                                            15
                                                                  originates from polypropylene, which was
16
      merge together and crystalize together.
                                                            16
                                                                  manufactured with inclusion of blue granules.
17
             So this also shows that it is
                                                            17
                                                                          Q. And then you list optical
      polypropylene, because in melted state, they're
18
                                                            18
                                                                  properties in polarized light, right?
19
                                                            19
      compatible. So they can recrystallize on their own.
                                                                          A. Yes. Which are very different
20
             But, it also indicates that the tool
                                                            20
                                                                  from anything else in the body, and this shows as
21
      was touching it when it was already present. So it
                                                            21
                                                                  well that it's polypropylene.
22
                                                            22
      means that it was forming in vivo, before it was
                                                                          Q. Okay. So those were the three
23
      burned.
                                                            23
                                                                  buckets I was talking about that were listed there
24
             Another feature shows that it was in
                                                            24
                                                                  in paragraph 6.
25
      vivo, is when I measure degradation layer and
                                                            25
                                                                          A. Yup. But then there is a
                                             Page 235
                                                                                                         Page 237
 1
      correlated it with time, it was gradually growing
                                                             1
                                                                  description in the pictures with figure captions
 2
      over the years. So the first time when you can see
                                                             2
                                                                  further going into the details.
 3
                                                             3
      it with light microscope, is probably about a year
                                                                          Q. Okay. I understand that.
 4
      or two in vivo. And then there is a rapid growth
                                                             4
                                                                          Have you just described for me all of
 5
                                                             5
      which later on plateaus and goes really slow, which
                                                                  the findings that you've made that lead you to
 6
      is biological response. I mean, it grows to a
                                                             6
                                                                  conclude that polypropylene degrades in vivo?
 7
      specific thickness, and then the rate of growth
                                                             7
                                                                          A. I think most.
                                                             8
 8
      slows down. So this also proves that it forms in
                                                                          Q. I think so.
 9
                                                             9
      vivo.
                                                                          Can you identify for me, any
10
                                                            10
              Another thing I said, I put new meshes
                                                                  peer-reviewed published literature, besides your
11
      in formalin, and kept them in formalin up to four
                                                            11
                                                                  own that we've looked at, that describe these three
12
      months, and then kept them -- and put them for
                                                            12
                                                                  findings that are set forth in paragraph 6?
13
      processing and examined them. There's no
                                                            13
                                                                          A. Okay. So you have to remind me
14
      degradation bark after four months. So, expose it
                                                            14
                                                                  which three findings; the blue granules?
15
      to formalin up to four months, it doesn't form
                                                            15
                                                                          Q. Blue granules, ability to track
16
      degradation. Again, if degradation is present and
                                                            16
                                                                  histological dyes, and optical properties in
17
      formalin doesn't cause it, it was present before
                                                            17
                                                                  polarized light?
18
                                                            18
                                                                          A. Blue granules, no. Polarized
      surgery.
                                                            19
19
              And then for transmission electron
                                                                  light has been used to identify foreign materials
20
      microscopy, the fact that inflammatory cells could
                                                            20
                                                                  for decades.
21
      migrate partially in the cracks, into crevices and
                                                            21
                                                                          Q. Okay. But not degradation?
22
                                                            22
      expand, that's what they normally do, inflammatory
                                                                          A. Including degradation.
                                                                          Q. Of polypropylene?
23
      cells go through very tight spots to migrate
                                                            23
24
      through the vessel walls. They try to do the same
                                                            24
                                                                          A. Not poly -- well, polypropylene
25
      thing into the cracks of degraded material, but
                                                            25
                                                                  is, no; because sutures were around. So what
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60 (Pages 234 to 237)

Page 238 Page 240 1 THE WITNESS: Specifically for 1 pathologists do, they see something, it's clear, 2 it's not sure if it's foreign or a native tissue, 2 polypropylene, yes, I'm the first one. 3 3 polarize and see what's the state of it. BY MS. BYARD: 4 4 Q. Let's talk a little bit about how Specifically for degradation bark, the 5 5 way I describe it, no. But, I mean, generally, specimens get to you from the surgical location, 6 6 all right? In order to understand it and breakdown pathologists identify foreign bodies, including 7 polypropylene sutures, and they assess the state 7 what you've said here in paragraph 6 a little bit 8 8 better. they are in. 9 9 Q. My question is more narrow than You would agree with me that all the 10 10 what you're responding to, okay? specimens that you've reviewed were excised during 11 11 My question is simply whether there is surgery by a physician, right? A. That's correct. 12 12 peer-reviewed published literature besides your own 13 that we've looked at, that describes finding of 13 Q. And apart from what's described in 14 14 degradation of polypropylene with polarized light? the operative report of the excision, you don't 15 MR. ORENT: Objection. Misstates the 15 know beyond that, what was done to remove the mesh, 16 16 opinions of Dr. Iakovlev. 17 17 THE WITNESS: As I said, the state of A. Specific details, no. The only 18 polypropylene sutures and the examination in 18 thing I need to assess as a pathologist, is acceptable for examination and to what degree I can 19 polarized light has been described before. Nobody 19 20 20 coined it as I did as a bark, and went into these examine it. 21 details, that's true. 21 Q. Okay. And my question is a little 22 22 But, was it used to see if different. 23 23 polypropylene is there and if it's in degraded My question is, beyond what's set forth 24 state or -- yes. 24 in the op report describing this excision 25 25 procedure, you don't know the details of what the Page 239 Page 241 1 1 BY MS. BYARD: surgeon did to remove that specimen, correct? 2 Q. Can you point me to an article 2 A. No, it's irrelevant to my 3 that talks about identifying degradation of 3 practice. I don't ask it even if there were other 4 polypropylene sutures through the use of polarized regular diagnostic specimens. 5 5 light? Q. Okay. So the answer to my 6 A. I'd have to search for it, but as 6 question is "no" --7 7 I said, I mean, generally the tool is there and for MR. ORENT: Objection. 8 diagnostic surgical pathologists they see foreign 8 BY MS. BYARD: material, they have to assess what state it is in. 9 9 Q. -- and you would also add that 10 10 it's not relevant to you? Q. Can you name an article for me, 11 A. That's correct. Doctor? 11 A. I cannot do it now, but I would 12 Q. Okay. And again, unless it's set 12 13 have to search for that, but... 13 forth in the operative report, you don't typically 14 14 know what instruments the doctor used to excise Q. Okay, thank you. 15 Similarly, can you give me the name of 15 this specimen, correct? 16 an article, a peer-reviewed published article, that 16 MR. ORENT: Objection. 17 talks about identification of degraded polypropylene 17 THE WITNESS: I can deduct it from what 18 by its ability to trap histological dyes? 18 I see. If I see cautery, then they used cautery. 19 19 MR. ORENT: Objection. If I see depth of the changes in the tissue and so THE WITNESS: That is also my 20 20 forth. 21 description. 21 So, essentially, what I do, I go by 22 22 what I see. And if something is different, then BY MS. BYARD: 23 Q. Okay. You are the only one who 23 there are specific features to assess what happened 24 24 has reported that finding, correct? to a specimen. 25 MR. ORENT: Objection. 25

61 (Pages 238 to 241)

	Page 242		Page 244
1	BY MS. BYARD:	1	and piecemeal not necrose sorry, I'm a little
2	Q. For instance, are you able to	2	bit.
3	discern whether the doctor used a scalpel or	3	If it's piecemealed resection and it's
4	Metzenbaum scissors?	4	raggedy, it's clear that it was difficult excision.
5	A. It doesn't matter to me. I mean,	5	If it's cleanly excised, no damage to it, I mean,
6	this is completely irrelevant.	6	it's clear that it was easy excision.
7	Q. Okay. So the answer to my	7	Q. In the litigation context, you
8	question is, no, you're not able to discern that,	8	don't review the depositions of the excising
9	right?	9	surgeons, right?
10	A. No, I don't know why you're asking	10	A. No.
11	me this.	11	Q. You don't speak to the excising
12	Q. Doctor, I just I just am asking	12	surgeons in the litigation context, do you?
13	you my questions. If you understand where they're	13	A. No.
14	coming from or not, is okay. But I just need	14	Q. Generally, though, you do know
15	answers so that we can move along, all right?	15	that doctors when excising specimens, need to grip
16	A. Okay.	16	the area of mesh that they're removing in order to
17	Q. Okay. So the answer to my	17	accomplish the surgery, right?
18	question is that you can't discern whether scalpel	18	A. Of course.
19	or scissors were used, for example?	19	Q. And unless it's set forth in the
20	MR. ORENT: Objection.	20	operative report, you don't know what
21	THE WITNESS: I can discern if it was	21	instrumentation was used to grip the mesh, correct?
22	hot or cold instrument.	22	A. No.
23	BY MS. BYARD:	23	Q. Similarly, to the extent that
24	Q. Okay, thank you.	24	distortions to the mesh occur as the doctor is
25	A. Or if it was crushing or sharp,	25	cutting and removing it, you're not able to tell
	Page 243		Page 245
1	that I can discern, but not beyond that.	1	whether that distortion occurred in vivo, or
2	Q. Thank you. And again, apart from	2	whether it occurred during this removal process,
3	what's set out in the operative report, you can't	3	
4			correct?
	identify what degree of force, if any, was used to	4	correct?  A That is not correct
	identify what degree of force, if any, was used to excise the specimen, correct?	4 5	A. That is not correct.
5	excise the specimen, correct?	5	<ul><li>A. That is not correct.</li><li>Q. For example, if you are given two</li></ul>
	excise the specimen, correct?  MR. ORENT: Objection.	5 6	A. That is not correct.  Q. For example, if you are given two specimens of mesh from a sling incision, you
5 6 7	excise the specimen, correct?  MR. ORENT: Objection.  THE WITNESS: I can only define the	5 6 7	A. That is not correct. Q. For example, if you are given two specimens of mesh from a sling incision, you couldn't say that the mesh was broken apart in the
5 6 7 8	excise the specimen, correct?  MR. ORENT: Objection.  THE WITNESS: I can only define the degree of manipulation instrument or other handling	5 6 7 8	A. That is not correct. Q. For example, if you are given two specimens of mesh from a sling incision, you couldn't say that the mesh was broken apart in the women's body before it was removed, right?
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	Page 246		Page 248
1	Q. And I think you said the longest	1	operating room to the laboratory?
2	that you put your control sample of virgin mesh in	2	A. After grossing. After I gross or
3	a jar of formalin was four months?	3	somebody gross the specimen, they take sections, so
4	A. Up to four months, yes.	4	it could fit in the cassettes. Then the cassettes
5	Q. So from the operating room, the	5	are loaded in the machine, and then there's a
6	specimen goes to pathology at the patient's	6	process of dehydration, saturation of tissue with
7	hospital or a local hospital typically, correct?	7	paraffin, and then the tissue can be cut when
8	A. That's correct.	8	paraffin solidifies and then it can be cut.
9	Um, if it is preserved, it goes to a	9	Q. Sometimes that dehydration and
10	lab through some channels. Some specimens are not	10	alcohol application and saturation with paraffin
11	preserved, they are discarded.	11	process happens in your laboratory for these
12	•	12	
	Q. If the sample or specimen is		litigation specimens, but sometimes they happen at
13	examined by a local pathologist, it's examined	13	the local hospital?
14	grossly and/or microscopically, typically, right?	14	A. That's correct.
15	A. There should be some form of	15	Q. How long does the process of
16	examination, gross or microscopic; yes, that is	16	applying increasing alcohol concentrations take?
17	correct.	17	A. The machine can be programmed
18	Q. Okay. You talked about the sample	18	differently, but roughly it runs about, the full
19	being preserved; what does that process entail?	19	cycle is anywhere between 12 to 24 hours, with
20	A. The main preservative is formalin,	20	different solutions. The short
21	so it's kept in formalin.	21	Q. Is it just alcohol?
22	Q. For the litigation context, you	22	A. No, no. There are serial
23	received samples through a company called	23	concentrations of alcohol increasing, and then
24	Steelgate, right?	24	xylene, and then xylene is replaced by paraffin.
25	A. Most of the samples came through	25	MR. ORENT: "Saline"?
	Page 247		Page 249
1	Page 247 Steelgate, sometimes it comes from law firms	1	Page 249 BY MS. BYARD:
1 2		1 2	
	Steelgate, sometimes it comes from law firms		BY MS. BYARD:
2	Steelgate, sometimes it comes from law firms directly or through Scisafe.	2	BY MS. BYARD: Q. X-Y-L-E-N-E?
2 3	Steelgate, sometimes it comes from law firms directly or through Scisafe.  Q. Spell that for me.	2 3	BY MS. BYARD: Q. X-Y-L-E-N-E? A. That's correct.
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Page 250 Page 252 1 thickness of the degradation layer; there was no 1 immunoperoxidase stains to do the S100 nerve 2 correlation between the storage time. It showed 0 2 observations? 3 3 A. Yes. Immunoperoxidase stain is correlation. It was exactly like minus 0.06 or 4 technique for immunostains where antibodies labeled 4 something like this. 5 5 While the correlation between in vivo against specific proteins. And then you choose 6 б antibody against what protein you want to stain. and thickness of the bark was .76 which is very 7 7 Q. You describe in your study with good for biological response. 8 8 Q. Is this data somewhere where I Dr. Carey, enzyme digestion for four minutes; what 9 could look at it? 9 is that, for a lay person? 10 10 A. The publication is almost A. It's the way you try to reverse 11 published. I mean, it's ready, it's written, so I 11 affect of formalin on tissue. So how formalin 12 need to just submit it. And, hopefully, when it is 12 preserves tissue, it crosslinks proteins in a way 13 submitted soon, and it will be accepted, then I can 13 that bacteria cannot degrade it anymore. 14 14 It's crosslinked, it ties up in a way present it to you. 15 15 Q. And until it's published, you that bacteria cannot digest it. But then some of 16 16 the epitopes, it points where antibody is wouldn't share that because it's considered 17 confidential by you at this point --17 connecting, are hidden in this sort of crosslink. 18 18 So you have to un-crosslink, open it A. Yes. 19 19 O. -- is that fair? up. And for some antigens, it's -- it's enzymes --20 A. Yes. At this point it would be, 20 usually, it is a protease, weakened protease. 21 21 Q. And that's only applied for four thoroughly. 22 22 O. Once the paraffin processing takes minutes? 23 place, the specimen is typically cut into a 23 A. It depends, I mean, these are 24 four-micron thick slice with what's called a --24 tested -- sometimes manufacturer gives 25 25 instructions, sometimes we have to adjust it. I A. Microtome. Page 251 Page 253 1 Q. Thank you. Sometimes for the 1 mean, it's a quality assurance process. We use 2 specimens that you reviewed in litigation, those 2 standard tissue to validate the stain and other 3 slices are made in your laboratory, but other times 3 things. 4 they've already been made by the local hospital; is 4 Q. For instance, you describe in your 5 5 study with Dr. Carey that the enzyme or the that right? 6 A. That's correct. 6 retrieval process is something like 36 minutes for 7 7 Q. And then at some point in time smooth muscle? 8 8 during this process from the operating room to your A. I mean, either manufacturer 9 laboratory, you apply stain, which you've talked to 9 recommended that time, or we, in the lab, 10 10 determined that this is optimal time for retrieval, me about? 11 11 A. That's correct. antigen retrieval. 12 Q. Does that take place after you've 12 Q. You also in this process of prepared these four-micron thick slides? 13 13 staining the slide and using enzyme digestion to 14 A. Yes. 14 examine the slide, or really to prepare the slide 15 15 Q. And there is a staining called for examination, you also incubate the slice? 16 hemotoxin and Eosin, H&E? 16 A. "Incubate" means when you apply 17 A. Eosin, yes. 17 antibody, you need to give it time to work to find 18 18 Q. Eosin? it; so this is incubation. 19 19 This time when you wait, apply antibody A. Um-hum. 20 20 Q. That's one stain that you might use? and wait until you can proceed to other steps. 21 21 A. It's a basic standard stain, first Q. So for this process of dehydration 22 22 and xylene replacement, and paraffin embedding and stain. Most commonly used in North America as an 23 initial stain. And most time it's the only stain 23 for enzyme digestion and incubation, are you 24 24 which is used. applying heat? 25 Q. You also performed staining with 25 A. 37 degrees, sometimes it's a

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Page 254 Page 256 1 little higher. I mean, there is a range of -- it 1 parts were -- and degraded were exposed to exactly 2 depends on what retrieval is done and how it is 2 the same environment, heating chemicals. 3 3 done. But there is a degree of heating involved in BY MS. BYARD: 4 Q. And I'm not making a distinction 4 some of the techniques. 5 5 Q. Celsius, 37 degrees celsius? between the degraded and -- the degraded bark as 6 6 A. 37 degrees celsius, sorry. I you've coined the term, and the non-degraded core. 7 completely forgot you're on a different scale. 7 I'm talking about the virgin samples of 8 8 Q. So as the specimen is undergoing mesh, off the shelf, that you examined? 9 paraffin embedding for 12 to 24 hours, it may be 9 A. Virgin tissue was exposed to 10 maintained at 37-degree celsius? 10 exactly the same temperatures and chemicals. 11 A. 37 or higher. I mean, depends. 11 Q. I'm talking about virgin mesh. 12 Sometimes there's no retrieval at all, it just 12 A. Virgin mesh. Um, virgin mesh, 13 stain it the way it is; without retrieval. So 13 sorry. Yes. 14 14 there is no temperature, and no, um, higher Q. It was, okay. Did you expose the virgin mesh to all 15 15 temperatures. 16 Q. If you were going to say that the 16 the same staining procedures that we've discussed? 17 specimens are subjected to heat up to a certain 17 A. H&E. 18 temperature, what would you -- what would be the 18 O. Just H&E? A. Yes. 19 "up to" amount? 19 20 A. 90 degrees centigrade, highest. I 20 Q. When you examine the mesh for the 21 don't think it will go beyond in any of the steps. 21 litigation cases for whether or not the sample 22 22 absorbs dye, are you just using H&E stain? O. And where would you use those 23 higher temperatures for processing? 23 A. I think it's incomplete question. 24 A. Paraffin. Usually, the highest 24 To observe what? 25 temperature would be melting point of a paraffin, 25 Q. In paragraph 6 where you talk Page 255 Page 257 1 about the absorption of the mesh of histological maybe 80 degrees, maybe 90, I'm not sure now. 1 2 Because I think if it's too high, the paraffin is 2 dyes? 3 brittle, it's melting point is high. If it's 3 A. No. H&E and trichrome, and even 4 lower, it becomes too soft. 4 immunoperoxidase, its counterstain was hematoxylin 5 5 and it stains the degraded layer. I would say probably closer to 80 than 6 90. But I'm not sure, I mean, it all depends. б Any stain, any histological, 7 Q. Were the samples of virgin mesh 7 histochemical stain, will stain it. 8 8 that you looked at for a control, and your Q. So what I want to understand is, 9 9 degradation observations, subjected to 80 to which dyes were applied to the virgin mesh, which 10 stains --10 90 degrees celsius? 11 11 A. Yes. I mean, that's only way to A. H&E. 12 embed it to melt paraffin. And, both the central 12 Q. -- were applied to the virgin 13 13 mesh, and then which stains were applied to the non-degraded part was also exposed. 14 14 mesh that you looked at for degradation? So I think there's internal control in 15 each slide, non-degraded part is exposed to exactly 15 A. For virgin mesh experiments, I 16 the same procedural steps. There's no dying in the 16 used only H&E. 17 center, it remains clear. Therefore, all 17 For specimens, and all pictures are 18 18 procedural steps have no effect on polypropylene there. I used H&E, trichrome stain, Gomori 19 19 trichrome stain, Masson trichome stain, Von Kossa degradation. 20 20 Q. My question was simply whether or stain, immunohistochemical stains. 21 21 not the samples were exposed to 80 to 90 degrees Q. So one difference between the 22 22 temperature, okay? virgin mesh samples, and the mesh samples that you 23 MR. ORENT: Objection. 23 examined for degradation that were surrounded by tissue, were the number of different stains that 24 24 THE WITNESS: Well, I mean, I just told 25 you that both virgin tissue and the non-degraded 25 you applied to those specimens, fair?

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	Page 260
1 MR. ORENT: Objection. 1 Actually, you don't	't want tissue to be
2 THE WITNESS: Could you repeat the 2 separated. You want tissu	
3 question? 3 BY MS. BY ARD:	
4 BY MS. BYARD: 4 Q. Okay. You di	
5 Q. Sure. So looking at specimens, 5 before you looked at the s	
6 mesh and tissue, you applied multiple different 6 way to do it?	
	jection. Compound asked
8 A. For some 8 and answered.	J
	Yes. That summarizes.
10 THE WITNESS: specimens, I only had 10 BY MS. BYARD:	
	en you're examining
12 BY MS. BYARD: 12 the mesh for degradation	
13 Q. Okay. But for the virgin mesh 13 are looking at the mesh w	
14 samples you only used H&E? 14 surrounding tissue, right?	
15 MR. ORENT: Objection. Asked and 15 A. Most of the time	me. Occasional
16 answered. 16 filaments are kind of stick	
THE WITNESS: That is correct. Because 17 cross section like the sli	•
18 there are no purpose for other stains. 18 off.	
19 BY MS. BYARD: 19 Q. Okay. And in	all the figures
Q. When you looked at mesh for 20 you've given us here in you	_
21 degradation, you never cleaned the samples to 21 samples are embedded in	=
22 remove the tissue, right? 22 A. Yes.	
23 A. No. 23 Q. As I understar	nd it, would these
Q. As a pathologist, are there 24 specimens that you receive	
processes that you would use to remove tissue from 25 oriented in the three-dime	
Page 259	Page 261
1 a foreign body? 1 specimen in different wa	ve right?
2 A. I don't understand the question, 2 A. Yes.	ys, 11giit.
1	knife of the microtome
4 Q. I was asking. I was asking you, 4 is cutting the specimen, y	
5 as a pathologist, are there processes that you 5 the meshes that are comp	
6 would use if you wanted to remove tissue from a 6 angled to the knife blade.	
	define as the plane of
8 A. No, not really. Because we cut 8 the mesh?	define us the plane of
9 through specimens, so it would be totally 9 Q. So, mesh has	a length a fiber
10 separated. 10 and it has a width of fibe.	•
O. Okay. There's a way to do that if 11 structure. right?	
Q. Okay. There's a way to do that if 11 structure, right? 12 you wanted to, though, right? 12 A. You mean inc	dividual mesh fibers
12 you wanted to, though, right? 12 A. You mean inc	dividual mesh fibers s filaments. So fiber
12 you wanted to, though, right? 13 A. I read an article, some 12 A. You mean included and article are some 13 or well, it's more or less	s filaments. So fiber
you wanted to, though, right?  12 A. You mean in  13 A. I read an article, some 14 researchers use separation to observe the surface, 14 and filament in this case	s filaments. So fiber
you wanted to, though, right?  12 A. You mean incompleted and article, some 13 A. I read an article, some 14 researchers use separation to observe the surface, 15 yes.  12 A. You mean incompleted and filament in this case 15 You mean individual and filament in this case	is filaments. So fiber is the same term. It is filaments, if I
you wanted to, though, right?  12 A. You mean included an article, some 13 or well, it's more or less or well, it's more	is filaments. So fiber is the same term. dual filaments, if I perpendicular or
you wanted to, though, right?  12 A. You mean included an article, some 13 or well, it's more or less or well, it's more	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape,
you wanted to, though, right?  12 A. You mean incomplete and filament in this case 14 researchers use separation to observe the surface, 15 yes. 16 But we don't have to, because we slice 17 across. For transmission electron microscopy, I  12 A. You mean incomplete and filament in this case 14 and filament in this case 15 You mean individually the surface, 16 know if they are entered 17 obliquely? Of course I'd	is filaments. So fiber is the same term. It is filaments, if I perpendicular or know. I mean, the shape, close to perfect
you wanted to, though, right?  A. I read an article, some 14 researchers use separation to observe the surface, 15 yes.  But we don't have to, because we slice 16 across. For transmission electron microscopy, I 18 got we're just cutting through it.  12 A. You mean individual and filament in this case 13 you mean individual and filament in this case 14 and filament in this case 15 You mean individual and filament in this case 16 know if they are entered 17 obliquely? Of course I'd 18 if it's perfect circle or other properties.	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape, close to perfect adicular shape.
you wanted to, though, right?  A. I read an article, some researchers use separation to observe the surface, yes.  But we don't have to, because we slice across. For transmission electron microscopy, I got we're just cutting through it.  Q. Okay. It's possible that you  12  A. You mean individual and filament in this case 13  You mean individual through it. 14  know if they are entered obliquely? Of course I'd if it's perfect circle or	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape, close to perfect idicular shape. in you have the
you wanted to, though, right?  A. I read an article, some researchers use separation to observe the surface, yes.  But we don't have to, because we slice researchers uses separation to observe the surface, but we don't have to, because we slice researchers use separation to observe the surface, yes.  But we don't have to, because we slice researchers use separation to observe the surface, yes.  You mean individuation this case know if they are entered obliquely? Of course I'd wif it's perfect circle or of the surface, if it's perfect circle or of th	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape, close to perfect adicular shape. n you have the n. So for specific
you wanted to, though, right?  A. I read an article, some researchers use separation to observe the surface, yes.  But we don't have to, because we slice across. For transmission electron microscopy, I got we're just cutting through it.  Q. Okay. It's possible that you haven't done it, because you didn't feel the need haven't done it, because you didn't feel the need  MR. ORENT: Objection.	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape, close to perfect adicular shape. n you have the n. So for specific
you wanted to, though, right?  A. I read an article, some researchers use separation to observe the surface, yes.  But we don't have to, because we slice across. For transmission electron microscopy, I got we're just cutting through it.  Q. Okay. It's possible that you haven't done it, because you didn't feel the need haven't done it, because you didn't feel the need  MR. ORENT: Objection.	is filaments. So fiber is the same term. dual filaments, if I perpendicular or know. I mean, the shape, close to perfect adicular shape. In you have the In. So for specific cause you can see it. Is itself, it may not

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Page 262 Page 264 1 Q. And the mesh might not be oriented 1 of angle from 90 degrees to almost, um, almost 2 in the specimen, along the length of the specimen, 2 parallel orientation, anywhere. 3 3 I mean, pretty much any specimen if right? 4 it's large enough, you will find a range of angles. 4 A. Let's separate. Filaments, 5 5 individual filaments and the mesh. Q. So not every slide is a 90-degree 6 cross section of all of the mesh fibers contained 6 Q. That's what I was trying to do. 7 You're the one who went to the mesh within the 7 in that section of the specimen? 8 8 larger specimen potentially being folded. A. That's correct. 9 Let's take out for now, just the 9 MR. ORENT: Objection. 10 fibers, the filaments of mesh itself? 10 BY MS. BYARD: 11 A. That's okay. 11 Q. Does polarized light reflect off 12 Q. So because you don't know how the 12 different thicknesses of material differently? 13 mesh is oriented in the specimen --13 A. I'm not sure exactly what you're 14 A. Mesh filament or the mesh? 14 asking. If it brightens, it will be different if Q. We'll get to that. 15 the thickness of the material is different? Yes. 15 16 So because you don't know how the mesh, 16 If it's getting thicker, there will be 17 as a whole, is oriented in the specimen, you 17 more material, it will -- to a certain degree, I 18 similarly don't know how the individual fibers are 18 mean, that's to a certain degree I mean, so... 19 oriented in the specimen --Q. It will get brighter or dimmer? 19 20 A. No, this is not correct. 20 A. If it's clear, it will get -- to a 21 Q. -- right? 21 certain degree, it will get brighter. When it's 22 A. I can go -- mesh filament is 22 really thin, the brightness will be lower and then around the structure. So if it's cut 23 23 it will build up. And then after a certain 24 perpendicular, there is a round cross section. If 24 thickness, it will not matter anymore. So it 25 it is oblique, then you get an oval, and then 25 reaches full capacity. Page 263 Page 265 1 sometimes you get a really long sort of cross Q. Okay. So if I was looking at a 1 thinner amount of material that was clear, under 2 section. 2 3 3 polarized light, it would be brighter or dimmer So just by the shape, I can tell you 4 exact, approximately what's angle. 4 than thicker amounts of that same material? 5 5 O. Do you measure each one of the A. If it's clear, because polarizable 6 mesh shapes that you look at to assure that they 6 materials may be clear or not clear, so then 7 7 are perfectly round? there is a --8 8 A. There is a bunch of different Q. It's clear in this hypothesis. 9 A. If it's clear, and it's really --9 shapes, and some of them are round, some of them 10 10 if it gets thicker -- I mean, start from very thin, are oval. So the more longer oval you get, the more angle -- I mean, more acute angle is. barely visible. So the brightness of the light 11 11 12 Q. And so the way that you've 12 will be dimmer. 13 represented mesh in your colorized figures is with 13 And then with increasing thickness, the 14 yellow, right? 14 brightness will be going up, up until it reaches 15 15 full capacity. I mean, beyond which it cannot get A. Yes. 16 Q. And many of those shapes, you'll 16 any brighter. And then there might be some 17 concede, are not perfect circles, they're ovals; 17 influence with light transmission and so forth 18 aren't they? 18 there so... 19 19 A. Yes. They are angled. Q. Okay. I think I understand, thank Q. And so when the knife of the 20 20 you. 21 microtome is cutting each specimen to create a 21 A. But these sections I cut all at 22 slide, each mesh fiber or filament is not being cut 22 four microns. All tissue within the one section is 23 at a 90-degree angle in every circumstance, 23 exactly the same thickness. 24 correct? 24 Q. Not if it's not cut at a 90-degree 25 A. That's correct. There is a degree 25 angle, right?

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Page 266
                                                                                                           Page 268
 1
              A. No, it's all four microns.
                                                              1
                                                                           And in none of these figures do we see
 2
              Q. If the material is oriented at an
                                                              2
                                                                   the entire circumference of the mesh filament, do
 3
                                                              3
       angle, and not completely 90 degrees --
                                                                   we?
 4
                                                              4
                                                                           A. No, because it doesn't fit. Well,
              A. It's still four microns.
 5
              O. -- to the knife --
                                                              5
                                                                   the thickness of this degraded layer is anywhere
                                                              6
 6
              A. It's four microns. Can I draw it?
                                                                   between two to six microns. Filament is up to
 7
                                                              7
                                                                   here. It wouldn't fit.
              Q. It's a three-dimensional space,
                                                              8
 8
       though.
                                                                           Q. Okay. So in the -- at the level
                                                              9
 9
              A. No, it's a slice. So if you get
                                                                   of magnification that you need to view this narrow
10
       slice like this, four microns. If you get slice
                                                             10
                                                                   margin, what you call the degraded bark, you're not
11
       like this, four microns. If you get slice like
                                                             11
                                                                   able to capture the entire circumference of the
                                                             12
12
       this, it's oblique, it's still four microns.
                                                                   mesh filament in your imaging?
13
              Q. But the way the material is angled
                                                             13
                                                                           A. Yes. This magnification size of
                                                             14
14
       within the specimen is tilted?
                                                                   filament is much larger, several pages larger. In
                                                             15
                                                                   some lower magnification, you can still see the
15
              A. Yes. But it's still four microns
16
                                                             16
                                                                   degraded layer, but it's much less details.
       thickness. The cross section is four microns
17
                                                             17
                                                                           Q. One question I had was how you're
       thick, it doesn't matter what orientation, it's
                                                             18
                                                                   able to tell that there isn't tissue interposed
18
       still four microns. Doesn't matter how you're in
19
       it, four microns. It's like a salami.
                                                             19
                                                                   over the edge of the filament, and your eye,
              Q. But if you look at it from looking
20
                                                             20
                                                                   through the microscope.
21
       up, you would be looking through less material on
                                                             21
                                                                           So if you're able to answer that, if
22
                                                             22
       the far edge of the material if it was oriented
                                                                   not I can rephrase.
23
       sideways?
                                                             23
                                                                           A. How do I see if there's no tissue
24
              A. Or the very edge, the very tip of
                                                             24
                                                                   overlapping with the filament? Sometimes it is,
25
                                                             25
                                                                   just play with focus. Because it goes like this.
       this, yes. It will be somewhat different, yes.
                                              Page 267
                                                                                                           Page 269
 1
              Q. Okay, thank you. Thank you.
                                                              1
                                                                   It's a different plane of focus, so you cannot
 2
              THE VIDEOGRAPHER: Excuse me, Counsel.
                                                              2
                                                                   focus on exactly the same. Even within four
 3
      I have to change the tape.
                                                              3
                                                                   microns, you can focus only within very narrow
                                                              4
 4
              MS. BYARD: Perfect, let's take a
                                                                   range.
                                                              5
 5
      break.
                                                                          So, essentially, you're looking at the
 6
              THE VIDEOGRAPHER: This marks the end
                                                              б
                                                                   slice which is much thinner than four microns.
 7
      of media number three in the deposition of
                                                              7
                                                                   Probably you'll be in the focus of a range of one
                                                              8
 8
      Dr. Vladimir Iakovlev.
                                                                   micron thickness only. The rest will be blurred.
 9
              We are going off the record at
                                                              9
                                                                          Like this picture, you mentioned 32.
10
                                                             10
                                                                   You see this is completely blurred. And it's
      5:28 p.m.
              -- RECESS AT 5:28 --
11
                                                             11
                                                                   probably just one micron deeper than this part.
12
              -- UPON RESUMING AT 5:38 --
                                                             12
                                                                   It's different plane, and it's out of focus, and
                                                             13
13
              THE VIDEOGRAPHER: Here begins media
                                                                   then you don't see any details. Little further
14
      number four in the deposition of Dr. Vladimir
                                                             14
                                                                   down, it will be just pink haze, from the breakoff.
                                                             15
15
       Iakovlev.
                                                                           Q. Okay. So in order to focus in on
16
              We're back on the record at 5:38 p.m.
                                                             16
                                                                   what you call the degraded bark, you have to focus
17
              BY MS. BYARD:
                                                             17
                                                                   in at a level where you are assured you're looking
                                                             18
18
              Q. Doctor, I have some relatively
                                                                   past the tissue?
19
                                                             19
      straightforward questions about the figures in your
                                                                          A. What do you mean, where it overlaps?
                                                                           Q. (Nods.)
      report related to paragraph 6. If you wouldn't
                                                             20
20
                                                             21
21
      mind turning with me to Figure 9C.
                                                                           A. Yes. I mean, I can even see -- I
22
              A. What page number?
                                                             22
                                                                   can focus on different layers of degraded material.
23
              Q. It's on page 33, sir. And I
                                                             23
                                                                   On deeper, some more superficial, because focusing
24
                                                             24
                                                                   depth is very narrow. As I said, within one micron --
       guess, really, this question refers to 9, 9A, 9B,
25
       9C, really all the way through to 16.
                                                             25
                                                                   with that magnification, it's very shallow.
```

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Page 270
                                                                                                       Page 272
 1
             Q. You would agree, though, that it
                                                            1
                                                                         THE WITNESS: I'm telling you.
 2
      is typical for there to be some tissue overlapping
                                                            2
                                                                         BY MS. BYARD:
 3
      the circumference of the mesh filament on cross
                                                            3
                                                                         Q. You're telling me, but I don't
                                                            4
 4
      section?
                                                                 have the underlying data, right?
 5
             A. No. Typical is contraction, so
                                                            5
                                                                         MR. ORENT: Objection.
 6
      tissue contracts during dehydration, it splits and
                                                            6
                                                                         THE WITNESS: That's correct.
 7
      goes away. Usually, the way when it overlaps, when
                                                            7
                                                                         BY MS. BYARD:
                                                            8
 8
      it lifts up, floats and sits on tissue.
                                                                         O. Okay. Looking at paragraph 7 of
 9
             But if it sits in situ, this should
                                                            9
                                                                 your report, sir, on page 6. You write that:
10
      contract and retracts. So usually there is a
                                                          10
                                                                            "The published literature
11
      separation. Sometimes there is not on edges, but
                                                          11
                                                                         indicates that the main
12
      overlap with the tissue is least common phenomena.
                                                          12
                                                                         complications of transvaginal mesh
13
             Again, any overlap in the field will
                                                          13
                                                                         devices leading to mesh excision are
14
      not be visible because of the depth of sharpness.
                                                          14
                                                                         chronic pelvic pain, pain with
      I can focus on the very narrow depth. You can have
15
                                                          15
                                                                         intercourse, parenthesis, [dyspareunia],
16
      15-microns difference with different layers, and if
                                                          16
                                                                         de novo, worsening urinary symptoms
17
      you have enough light which is passing through, you
                                                          17
                                                                         and mucosal erosion, parenthesis,
18
      can gradually see layer by layer, and steady
                                                          18
                                                                         [mesh exposure]."
                                                                         Which articles are you relying on for
19
      details within these 15 microns.
                                                          19
20
             Q. Have you continued soaking that
                                                          20
                                                                 that statement?
21
      virgin mesh or other virgin mesh samples in
                                                          21
                                                                         A. Clinical.
22
                                                          22
      formalin?
                                                                         Q. Are there articles in your list of
23
             A. Yeah, I have some still sitting in
                                                          23
                                                                 materials reviewed that you can point me to for
24
      formalin.
                                                          24
                                                                 that proposition?
25
                                                          25
             Q. When was the last time that you
                                                                         A. The regular complications? Yes.
                                            Page 271
                                                                                                       Page 273
 1
      examined them for degradation?
                                                                 I mean, there are some clinical articles there.
 2
             A. Sometime during summer. But
                                                            2
                                                                        Q. Any in particular that you would
 3
      sometimes I completely use up the sample, so I have
                                                            3
                                                                 cite for support for that proposition?
 4
      to start the process again, so it's not -- the
                                                                        A. I would have to check these papers
 5
      first mesh was exposed, I think last fall. But I
                                                            5
                                                                 again, sorry. Because it's been quite sometime. I
 6
      don't think I have samples from that time, so there
                                                            6
                                                                 don't remember exactly which article specifies,
                                                            7
 7
      will be -- I just have dates written on the jars,
                                                                 but...
 8
                                                            8
                                                                        Q. Now in contrast, your data that
 9
             Q. Okay. And the longest still it's
                                                            9
                                                                 you publish with Dr. Carey indicated that the
10
                                                          10
      been in formalin is four months?
                                                                 number one reason for excision in the samples that
11
             A. Four months. It's way beyond the --
                                                          11
                                                                 you reviewed there, were for exposure, correct?
12
      when I was writing this manuscript, we talk about,
                                                          12
                                                                        A. You mean mucosal exposure? Yes.
13
      about 25 percent of the samples had exposure time
                                                          13
                                                                        Q. Okay. If I were to ask you what
14
      less than a month. And about 8 or 10 percent of
                                                          14
                                                                 the rate in the medical and scientific literature
15
      the specimens I examined had exposure to formalin
                                                          15
                                                                 of excision for dyspareunia was, compared to the
16
      less than 72 hours. And they still showed the same
                                                          16
                                                                 rate of excision for dyspareunia in your 120
17
      degradation layer, so...
                                                          17
                                                                 specimens, you couldn't cite me those numbers,
18
             Q. And you're referring to one of
                                                          18
                                                                 could you?
                                                          19
19
      your published studies?
                                                                        A. I would have to go through papers
20
             A. In preparation. But I'm just
                                                          20
                                                                 and -- the rate will be different in each paper,
21
      telling you the date. So four months is overkill
                                                          21
                                                                 and there is no such thing as the same rates. So
22
                                                          22
      by many fold.
                                                                 there will be a range of rates.
23
             Q. Okay. And that's not data that we
                                                          23
                                                                        Q. And that analysis hasn't been
24
                                                          24
                                                                 completed, has it?
      have yet, right?
25
             MR. ORENT: Objection.
                                                          25
                                                                        MR. ORENT: Objection.
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69 (Pages 270 to 273)

	Page 274		Page 276
1	THE WITNESS: What do you mean, which	1	A. No, but
2	analysis?	2	Q. Okay, thank you.
3	BY MS. BYARD:	3	You write here in paragraph 7, that
4	Q. Comparing the range of reported	4	this is consistent with random sampling since the
5	rates of dyspareunia as the reason for excision in	5	samples had variable sources and manufacturers; do
6	the published literature, with the rate of excision	6	you see that?
7	for dyspareunia in your sample size of 120	7	A. Yes, they were coming from
8	specimens?	8	different sources, from they were of different
9	A. If I published this comparison?	9	manufacturers. They were excised for different
10	No, I have not published this comparison.	10	reasons. The range of patient demographics was
11	Q. And you haven't done that	11	large.
12	comparison yet, either, right?	12	Q. You haven't set up a registry,
13	A. Well, roughly I estimated.	13	though, for mesh excisions in the transvaginal mesh
		14	-
14	Because you can see in the papers what is		example like you have for hernia mesh in your study
15	percentage of those excised for where is it?	15	with Dr. Bendavid, right?
16	Q. It was Exhibit 1198.	16	A. No. Those samples are obtained
17	A. So if we split now, see I have	17	prospectively, these samples were obtained
18	I had 67 percent exposure, 56 percent pain, and	18	retrospectively.
19	overlap between them, 33 percent.	19	Q. And the sources were threefold.
20	Q. That was for 24 specimens, though?	20	They were either St. Michael's, they were other
21	A. Yeah, that was a pool size in	21	hospitals, and they were from the Plaintiffs'
22	that. If you're asking for complete set, no. And	22	lawyers through various
23	this set is growing every day, I mean I'm receiving	23	A. But when they come from lawyers,
24	samples, so	24	they're not coming from one specific individual.
25	Q. So for the set of 120 specimens,	25	They're coming from different excising surgeons,
	Page 275		Page 277
1	you can't tell me what the rate of complications	1	different states, different hospitals of you
2	were prompting the revision surgery, right?	2	make it sound as if lawyers, just one person, one
3	MR. ORENT: Objection.	3	clinician and one lab, no. It's all over, you know
4	THE WITNESS: I can estimate the range	4	that.
5	anywhere from 30 to 50 percent, somewhere. It	5	Q. And your research on hernia repair
6	depends on the I mean, again	6	mesh, you didn't receive samples from Plaintiffs'
7	BY MS. BYARD:	7	lawyers, right?
8	Q. You don't have those numbers or	8	MR. ORENT: Objection.
9	those statistics analyzed yet, correct?	9	THE WITNESS: Which research?
10	A. Not for the total number of	10	BY MS. BYARD:
11	specimens I received by today. I mean, I	11	Q. The study that you published with
12	initially, as for this study, I did analysis; and	12	Dr. Bendavid?
13	then I think I did analysis sometime in between.	13	A. The SIN paper? No, there was no
	then I think I the analysis sometime in between.		
14	•	14	
	But I mean, I have not done it like yesterday Q. Okay.		litigation cases in this paper.
14	But I mean, I have not done it like yesterday Q. Okay.	14	litigation cases in this paper.  Q. Paragraph 8 continues:
14 15	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive.	14 15	litigation cases in this paper. Q. Paragraph 8 continues: "Pain is reported as the most
14 15 16	<ul> <li>But I mean, I have not done it like yesterday</li> <li>Q. Okay.</li> <li>A for all specimens I receive.</li> <li>Q. The numbers you can quote for me</li> </ul>	14 15 16 17	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh
14 15 16 17 18	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that	14 15 16 17 18	Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature
14 15 16 17 18 19	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published	14 15 16 17 18 19	Itigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I
14 15 16 17 18 19 20	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198?	14 15 16 17 18 19 20	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."
14 15 16 17 18 19 20 21	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198? A. This is just the paper in front of	14 15 16 17 18 19 20 21	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."  Do you see that?
14 15 16 17 18 19 20 21 22	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198? A. This is just the paper in front of me. I might have the number on the spreadsheet in	14 15 16 17 18 19 20 21 22	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."  Do you see that?  A. That's correct.
14 15 16 17 18 19 20 21 22 23	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198? A. This is just the paper in front of me. I might have the number on the spreadsheet in my log of specimens.	14 15 16 17 18 19 20 21 22 23	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."  Do you see that?  A. That's correct.  Q. Which study are you relying on for
14 15 16 17 18 19 20 21 22	But I mean, I have not done it like yesterday Q. Okay. A for all specimens I receive. Q. The numbers you can quote for me today are from these 24 samples that are that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198? A. This is just the paper in front of me. I might have the number on the spreadsheet in	14 15 16 17 18 19 20 21 22	litigation cases in this paper.  Q. Paragraph 8 continues:  "Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."  Do you see that?  A. That's correct.

70 (Pages 274 to 277)

Page 278 Page 280 1 where the pain was higher. Sometimes there are 1 entrapped in tissue that was never exposed to mesh, 2 other -- pain is a very subjective subject, and 2 3 3 sometimes it's not assessed. There is no primary A. No, this is not correct. If you 4 4 goal of the studies to assess pain, so they just take tissue as a general, there cannot be provide statistics. When the study is more focused entrapment because there is no tight area. 6 on pain, the numbers might be higher. So it's a 6 Entrapment happens in specific anatomical locations 7 7 where there is a tunnel, or there is a compartment. range. 8 8 Q. And the studies that you reviewed, I'm talking about normal, spontaneously occurring 9 9 what was the range of reported pain as a reason for sort of entrapment or tunnel syndromes. 10 excision? 10 This is not happening in, in tissue as 11 A. You mean percentage-wise? I don't 11 we talk about it. It's like a tunnel, usually 12 remember now, but I mean there were a number of 12 surrounded by some kind of winding, synovial 13 studies which showed pain as a first -- the number 13 winding of the place, tight spot where nerves pass 14 14 was higher, higher than anything else. 15 15 Q. Are you referring to hernia mesh Q. So if I understand your testimony 16 16 literature or transvaginal mesh literature? correctly, you can have nerve entrapment in the 17 A. Transvaginal mesh. And this is 17 body, even if there's not any mesh, against certain 18 just complication, it's not a reason for excision. 18 anatomical structures, or tunnels, or compartments 19 19 You see, if you read this, "the pain is as you've described it? 20 the most frequent complication." So if you go 20 MR. ORENT: Objection. 21 through it, it may go up to 30 percent, even higher 21 THE WITNESS: I mean, usually there is 22 22 in some literature. Some literature it goes -- in some degree of pathology called changes in the 23 some publications it goes lower. 23 area. It's not normal to have an entrapment 24 Q. As you were reviewing the medical 24 syndrome. 25 literature on complications of transvaginal mesh, 25 Page 279 Page 281 1 1 did you keep any notes on what the reported rate of BY MS. BYARD: 2 complication was for different symptoms? 2 Q. Sure. But what I want to focus on 3 A. No. Because I wasn't writing a 3 here are abnormal pathological findings that are 4 paper for that specific, it was just a memory of my 4 mechanisms for pain. 5 5 understanding. And I want to focus on abnormal 6 Q. Do you agree that innervated 6 pathological findings that are mechanisms for pain, 7 7 tissue, anywhere in the body, can be subject to and whether those mechanisms exist without mesh? 8 8 potential pain mechanisms of direct irritation to A. In the vaginal area, no. There 9 9 the nerves? are no anatomical locations, or specific anatomical 10 10 A. Yes. structures to cause nerve entrapment without mesh. 11 11 Q. Entrapment? Q. Without mesh you can never have 12 A. Entrapment in normal tissue? 12 nerve entrapment in the vagina; is that your 13 Q. (Nods.) 13 testimony? 14 A. If entrapment happens, it's 14 MR. ORENT: Objection. 15 abnormal. I mean, if you assume that there are 15 THE WITNESS: If there is no mesh and 16 places in the body which can cause entrapment 16 there is no other pathological condition, like a 17 syndromes, the entrapment itself becomes abnormal. 17 tumor or something else, it cannot happen. 18 BY MS. BYARD: Q. Sure. And I'm talking about 18 19 19 Q. Okay. So if there is a tumor you innervated tissue anywhere in the body can present 20 20 a finding of entrapment on histological examination? can have nerve entrapment? 21 A. No, it cannot. Entrapment, in 21 A. That's correct. With tumor, there 22 22 will be little bit different mechanisms. But there normal circumstances, occurs in tight spaces where 23 nerves pass by. So these are very specific 23 will be effected nerves. 24 anatomical locations. 24 Q. Okay. If there's another foreign 25 Q. It's possible for nerves to be 25 body besides the mesh in the vagina, there could be

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	Page 282		Page 284
1	nerve entrapment?	1	BY MS. BYARD:
2	A. If there is foreign body with	2	Q. That's a very fair point. The
3	compartment.	3	entire reason you have identified these potential
4	Q. Okay. Innervated tissue anywhere	4	pain mechanisms with mesh, is because these are
5	in the body can be exposed to pain mechanisms that	5	well understood mechanisms for pain in the
6	are inflammatory in nature, right?	6	literature, apart from any findings related to
7	A. Spontaneously occurring	7	mesh, correct?
8	inflammatory conditions, that's what you mean?	8	A. Yes. But, when I examine
9	Q. Any sort of inflammatory mechanism	9	specimens, I don't find anything else except for
10	of pain.	10	changes related to the mesh. I don't find the
11	MR. ORENT: Objection. Vague.	11	tumor, I don't find musculitis, which can cause
12	THE WITNESS: As we stated before, as I	12	necrosis of the vessels.
13		13	
14	stated before, inflammation alters sensitivity	14	So, part of my job as a pathologist, is
15	threshold.	15	to rule out other conditions. And then I see only
	So any inflammation can build up, so		changes which are related to the mesh.
16	the basis for pain, or cause pain if it's	16	Q. As a part of your practice,
17	sufficiently high enough.	17	though, in the litigation context, if you receive a
18	BY MS. BYARD:	18	specimen that's a uterus, and clearly not mesh, you
19	Q. Can compression by edema act as a	19	don't examine it?
20	mechanism for pain for tissue with nerve ingrowth,	20	A. I do examine it.
21	even when there is no mesh present?	21	Q. You do?
22	A. If it's enclosed compartment	22	A. I do, yeah. If I receive a
23	well, see, edema, if there's no walls of a	23	specimen, I look through the microscope.
24	compartment, edema will expand further. If it	24	Q. And do those findings make their
25	grows rapidly, it may cause some discomfort or	25	way into a report that's disclosed to us?
	Page 283		Page 285
1	pain. If there is no compartment, edema will	1	MR. ORENT: Objection.
2	and if it goes slowly, it will just be painless	2	THE WITNESS: I don't remember now.
3	edema. But the problems are when the edema goes	3	BY MS. BYARD:
4	faster; or, if it occurs in enclosed space.	4	Q. Withdrawn.
5	So you need to set some pathological	5	In the absence of mesh, there can also
6	condition. To form this walls of compartment, or	6	be mechanical irritation of receptors, right?
7	place foreign body, and then, to cause edema. And	7	A. Mechanical, if it's normal degree
8	then edema would occur in an enclosed compartment.	8	=
		"	of stimulation, it will not cause pain. If it's
9	Q. So in certain pathological	9	of stimulation, it will not cause pain. If it's abnormal degree, if it's high enough, it will cause
9 10	Q. So in certain pathological conditions, in the absence of mesh, compression by		
		9	abnormal degree, if it's high enough, it will cause pain. That's how
10	conditions, in the absence of mesh, compression by	9 10	abnormal degree, if it's high enough, it will cause
10 11	conditions, in the absence of mesh, compression by edema can cause pain?	9 10 11	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly.
10 11 12	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.	9 10 11 12	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh.
10 11 12 13	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.	9 10 11 12 13	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay.
10 11 12 13 14	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:	9 10 11 12 13 14	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your
10 11 12 13 14 15	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?	9 10 11 12 13 14 15	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch.
10 11 12 13 14 15	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema	9 10 11 12 13 14 15 16	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write:
10 11 12 13 14 15 16	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which	9 10 11 12 13 14 15 16	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with
10 11 12 13 14 15 16 17	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.	9 10 11 12 13 14 15 16 17	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly
10 11 12 13 14 15 16 17 18	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.  Q. Thank you.  Is the same true for ischemia?	9 10 11 12 13 14 15 16 17 18	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women."
10 11 12 13 14 15 16 17 18 19 20	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.  Q. Thank you.  Is the same true for ischemia?  MR. ORENT: Objection.	9 10 11 12 13 14 15 16 17 18 19 20	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that?
10 11 12 13 14 15 16 17 18 19 20 21	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.  Q. Thank you.  Is the same true for ischemia?  MR. ORENT: Objection.  THE WITNESS: For ischemia, yes.	9 10 11 12 13 14 15 16 17 18 19 20 21	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that? A. Yes.
10 11 12 13 14 15 16 17 18 19 20 21 22	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.  Q. Thank you.  Is the same true for ischemia?  MR. ORENT: Objection.  THE WITNESS: For ischemia, yes.  Again, that's why I can state that this has	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that? A. Yes. Q. What's the difference, in your
10 11 12 13 14 15 16 17 18 19 20 21 22 23	conditions, in the absence of mesh, compression by edema can cause pain?  MR. ORENT: Objection.  THE WITNESS: That's correct.  BY MS. BYARD:  Q. Even in the absence of mesh?  A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.  Q. Thank you.  Is the same true for ischemia?  MR. ORENT: Objection.  THE WITNESS: For ischemia, yes.	9 10 11 12 13 14 15 16 17 18 19 20 21 22	abnormal degree, if it's high enough, it will cause pain. That's how Q. Yes. Exactly. A take a hammer and then it will, it will hurt without mesh. Q. Okay. A. But if you just press it with your finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that? A. Yes.

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Page 286 Page 288 1 A. Clinical pathological correlation. 1 excise, you cause damage, and there is more 2 So when I receive a specimen, and described as 2 scarring. Because when you do multiple procedures 3 3 removed for reasons of pain, as I said, I examine throughout, the scar is there. So there might be 4 4 it for pathological findings, I rule out natural some residual changes in there. So the initial 5 5 occurring non-mesh-related conditions, then examine cause of these changes would be still mesh. 6 6 what happened in the mesh. So, that's what it How do you separate all of this? And 7 7 meant. how do you ascertain completeness of excision? How 8 8 Q. Okay. And so it's not as if they are certain that the postexcision changes are 9 9 you're looking at a pathological -- a pathology not residual changes which occurred while mesh was 10 10 slide and saying, "aha, it was this edema that there? This is difficult. 11 caused all this pain that she reported." Right? 11 BY MS. BYARD: 12 MR. ORENT: Objection. 12 Q. You would agree that correlation 13 THE WITNESS: See, when I receive a 13 isn't causation, though, wouldn't you? 14 14 specimen, I know that there was pain, and it's MR. ORENT: Objection. 15 15 indicated that -- sometimes I look at the history THE WITNESS: See, when you use 16 16 causation, do you use it in -- let me ask, I mean, later. So I know that there was pain, and I do 17 clinical pathology called correlation. 17 just to clarify this. 18 18 When you use word "causation," do you You cannot -- it's not a game, I mean, 19 19 it's a diagnostic process. You have to take all mean "prediction"? Or correlation of clinical 20 20 information available to you and then correlate. picture with the pathological findings? 21 Clinical investigation was done because 21 BY MS. BYARD: 22 22 of pain, they narrowed down problem to the excised Q. I guess maybe the better way to 23 23 mesh, I received a specimen. So I already know ask it is that the word you used here was 24 that there was a problem, complication, that's why 24 "correlate," right? Not "cause"? 25 it was excised. 25 A. And I explain it. Correlation is Page 289 Page 287 1 Then I try to figure out what was 1 clinical pathology calculation. Patient comes with 2 causing it, what is abnormal in the specimen which 2 complication, symptoms. So that's where clinical 3 3 was removed as a part of treatment of the part comes in. And there's investigation, there's complications, or patient's symptoms. And then I 4 narrowing down, and then I examine the specimen to 5 5 rule out naturally occurring, I don't see it, and see what is abnormal in it. So this is diagnostic 6 then I see this. 6 process and treatment process. 7 7 And then, if somebody tells me, "I have If you're talking about prediction, 8 8 what can happen in the future is something a pain." And I examine the specimen, and there is 9 9 mesh with edema, with nerve ingrowth, this is the occurring now, that's not how medicine works. 10 10 cause of pain. Because there is nothing else in So the correlation here, correlation 11 the specimen which would explain it. 11 between what was clinically seen abnormal, and what 12 BY MS. BYARD: 12 I see in the microscope. 13 Q. Now, if that patient's pain 13 Q. So you're relying, in large part 14 14 then, on the clinical determination that's made by continues after that mesh is excised, you can then 15 agree with me that the edema, or the foreign body 15 the treating physician, that the doctor and the 16 inflammation can no longer be considered the cause 16 patient should at least try to excise the mesh to 17 17 of those symptoms, right? address the patient's symptoms, right? 18 18 MR. ORENT: Objection. A. Yes. 19 19 THE WITNESS: If entire mesh is excised Q. You also write that: 20 20 without damage to the tissue, which is "Placement of vaginal tissue --" 21 21 hypothetical, I don't think most of the meshes can and I'm looking at paragraph 9 now, 22 22 be excised completely, or completeness of excision Doctor. "-- is associated with a 23 can be as certain. So the first difficult part of 23 higher risk of chronic pain issues 24 the statement. 24 than the placement of abdominal mesh --25 The second difficulty is that when you 25 abdominal hernia mesh." Excuse me.

73 (Pages 286 to 289)

	Page 290		Page 292
1	A. That's correct.	1	it's personal experience of each individual.
2	Q. And what literature are you citing	2	But the studies who studied further,
3	for that proposition?	3	how it happens with inflammatory mediators and
4	A. Again, clinical literature. Being	4	other things, yeah, they are there.
5	in the hernia is lower, somewhere in the range from	5	Q. There are studies that exist?
6	about 10 percent or so, but for transvaginal meshes	6	A. There should be at least in that.
7	it can go up to 30 percent.	7	Q. Okay. Are there studies looking
8	Again, it's very, very difficult to	8	more specifically at inflammation and foreign body
9	compare the studies, because they use different	9	reaction in the presence of mesh, and whether that
10	questionnaires and different approaches.	10	heightens the sensitivity threshold of pain
11	Q. And are you talking about rates of	11	receptors?
12	chronic pain as a complication overall, or is it	12	A. It's almost like narrowing down
13	complication leading to excision in this statement?	13	something to a specific area, like could there be a
14	A. Complication overall.	14	doctor for a little right finger.
15	Q. We talked earlier about how the	15	Q. The answer is, "no," right?
16	vagina compared to the abdominal wall, as a	16	A. There are studies which study
17	nerve-rich environment, right?	17	inflammation, in general. I mean, there's a
18	A. Yes.	18	physician or any thinking person, you can apply it
19	Q. And you would also agree with me	19	to any areas so
20	then, that the vagina as an area of the body is	20	Q. So the answer to my question is,
21	associated with a higher risk of chronic pain	21	no, the literature doesn't get that specific,
22	compared to the abdomen, because it is a more	22	right?
23	nerve-rich environment, right?	23	MR. ORENT: Objection.
24	A. Yes.	24	THE WITNESS: Not that narrow.
25	Q. And that's true in the absence of	25	THE WITNESS. Not that harrow.
	`	123	
	Dage 201		Dage 293
1	Page 291	1	Page 293
1	mesh, too, isn't it?	1	BY MS. BYARD:
2	mesh, too, isn't it? A. Yes.	2	BY MS. BYARD: Q. Thank you. Let's look at page 8,
2	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with	2	BY MS. BYARD: Q. Thank you. Let's look at page 8, please.
2 3 4	mesh, too, isn't it?  A. Yes.  Q. You conclude paragraph 10, with the statement that:	2 3 4	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the
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	Page 294		Page 296
1	Q. Okay. And the same thing is true	1	A. Possibly in some locations, yes.
2	for scar tissue, right? We know that all mesh will	2	But when I see it in the meshes, everything outside
3	be present with scar tissue, and yet not all women	3	of mesh is collapsed, and then vessels in the folds
4	with mesh experience pain?	4	of the mesh are dilated.
5	MR. ORENT: Objection.	5	So, therefore, I have internal control.
6	THE WITNESS: See, this is difficult.	6	I see what is outside of the mesh and I see what is
7	Because I don't actually have the specimens from	7	inside of the mesh, it's different.
8	women who for sure didn't experience pain, or	8	Q. You've looked at about 120
9	didn't experience any complications. This would be	9	specimens of transvaginal mesh at the time that you
10	an autopsy series, which is difficult.	10	authored your report.
11	So all cases I receive, they have	11	Do you have any statistics that you can
12	complications, all have scars. If those who never	12	cite for me for the rate of dilated and congested
13	have any complications, how much of scarring	13	vessels in non-scarred vaginal tissue that you have
14	there would be scar, if there is a different extent	14	examined in your course as a pathologist.
15	of scarring, I don't know.	15	A. See, normally, you don't see
16	BY MS. BYARD:	16	congestion. Congestion of the vessels is not
17	Q. In fact, let me rephrase that.	17	normal. I mean, there has to be something which is
18	Strike that.	18	causing it. So if it's normal tissue if I quote
19	The fact that women can have scarring	19	it "normal," it means that there are no
20	because of mesh, but not experience pain, tends to	20	pathological findings.
21	call into question, the association between the	21	If I see congestion, and some other
22	presence of that scar tissue around the mesh and	22	changes, I mean, this would not be perfectly
23	pain, doesn't it?	23	abnormal. I mean, there might be some bleeding due
24	A. It contributes. The scar itself,	24	to surgery or something else.
25	wouldn't be a problem. But scar with mesh, with	25	Q. You can't quote a rate then
	Dago 20E		
	Page 295		Page 297
1	innervation, with connection to other areas, then	1	Page 297 because you don't see it typically; is that what
1 2	_	1 2	_
	innervation, with connection to other areas, then the whole complex of changes, this leads to pain.  Q. Well, from your research you've		because you don't see it typically; is that what you're saying?  A. What do you mean, rate of what
2	innervation, with connection to other areas, then the whole complex of changes, this leads to pain.	2	because you don't see it typically; is that what you're saying?  A. What do you mean, rate of what happens with
2	innervation, with connection to other areas, then the whole complex of changes, this leads to pain.  Q. Well, from your research you've concluded that all mesh will have innervation, right?	2 3 4 5	because you don't see it typically; is that what you're saying?  A. What do you mean, rate of what happens with  Q. How often those findings are
2 3 4	innervation, with connection to other areas, then the whole complex of changes, this leads to pain.  Q. Well, from your research you've concluded that all mesh will have innervation, right?  A. Transvaginal?	2 3 4 5 6	because you don't see it typically; is that what you're saying?  A. What do you mean, rate of what happens with  Q. How often those findings are present in non-mesh vaginal specimens?
2 3 4 5	innervation, with connection to other areas, then the whole complex of changes, this leads to pain.  Q. Well, from your research you've concluded that all mesh will have innervation, right?	2 3 4 5 6 7	because you don't see it typically; is that what you're saying?  A. What do you mean, rate of what happens with  Q. How often those findings are present in non-mesh vaginal specimens?  A. I don't see it.
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1	Page 298		Page 300
1	congestion. If it's a healthy, elective procedure	1	mesh, muscle contraction results in
2	for hysterectomy, when they do some trimming of the	2	pulling of the entire mesh."
3	vagina, and then they get vaginal cuff, there is no	3	Do you see that?
4	congestion.	4	A. Yes.
5	BY MS. BYARD:	5	Q. Can you point me to any published
6	Q. Okay.	6	articles that show muscle contraction pulling on
7	A. No edema, no congestion, no	7	the mesh?
8	inflammation, is pristine tissue.	8	A. No, it has not been specifically
9	Q. And that's for a patient who's	9	studied in that specific sequence as you word it.
10	undergoing surgery electively, not because the	10	Q. You could design an experiment
11	uterus or surrounding organs, the ovaries, were	11	where you could look at muscle contraction in its
12	identified as being a potential cause of that	12	relationship to mesh, couldn't you?
13	woman's complaints, right?	13	÷ ,
14		14	A. What I do see, when I can tell you
15	A. There are complaints. I mean,	15	that if the muscle strength is viable, so it's
	there is a reason for hysterectomy. Usually it's	16	contractile. Because see, with a muscle, if it
16	dysmenorrhea or just	1	doesn't if it degenerates, it's not contract
17	Q. Heaviness?	17	anymore.
18	A. Excessive bleeding in perimenopausal	18	If it's healthy muscle, it will
19	periods, so they don't want to have to take	19	contract. So those muscle fibers or bundles, I see
20	drugs, so	20	in the mesh, they're healthy. Therefore, they
21	Q. Okay. You write in paragraph 13	21	contract.
22	about muscle relationships with mesh; are you with	22	Q. As far as how the mesh is then
23	me?	23	pulled by that muscle contraction, you could design
24	A. Yes.	24	an experiment, though, looking at, for instance,
25	Q. Can striated muscle grow within	25	3D ultrasound technology?
	Page 299		Page 301
1	the mesh structure?	1	A Oh if the mesh is marring during
2		_	A. Oh, if the mesh is moving during
1 -	<ul> <li>A. That's a difficult question.</li> </ul>	2	movements, and yeah, you can do it. I mean, you
3	A. That's a difficult question.  Technically, muscle itself cannot grow through		<u> </u>
	•	2	movements, and yeah, you can do it. I mean, you
3	Technically, muscle itself cannot grow through	2	movements, and yeah, you can do it. I mean, you can see well, as long as mesh is mobile. If
3 4	Technically, muscle itself cannot grow through the or in large amount, cannot grow through	2 3 4	movements, and yeah, you can do it. I mean, you can see well, as long as mesh is mobile. If it's so tight that it's not mobile anymore, like if
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Technically, muscle itself cannot grow through the or in large amount, cannot grow through mesh.  So there has to be a combination of either mesh placement into the muscle, which is done, we know. Or migration of the mesh into the muscle, and a degree of muscle regeneration in the folds or in the so it would be a combination of factors, how the mesh how the muscle strands become inside the mesh pores or folds.  Q. And you can't say when you look at a specimen, how that muscle and mesh got to where they are?  A. Depends. In some specimens, the mesh just cuts through the muscle, and you see the trail of the muscle, it just sifts through it.  Then I can say for sure the mesh migrated into the muscle, it left behind. But now muscle is interrupt, because mesh just went through it. But	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	movements, and yeah, you can do it. I mean, you can see well, as long as mesh is mobile. If it's so tight that it's not mobile anymore, like if it's saw it here in between pubic bones, then it will not be mobile. But it doesn't allow that muscle is trying to contract, it just cannot move it anymore because it's so immobile.  Q. And you're talking about various scenarios that you could understand based on your training and experience, correct?  A. That's correct.  Q. You're not talking about findings that you've seen based on an experiment using, for instance, 3D ultrasound technology that you, yourself, have performed, right?  A. No. I'm basing what I see on the microscope. If it's healthy muscle, within the mesh, completely surrounded by the mesh, it's contraction will cause movement of the muscle.  Q. And you haven't tested your
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Technically, muscle itself cannot grow through the or in large amount, cannot grow through mesh.  So there has to be a combination of either mesh placement into the muscle, which is done, we know. Or migration of the mesh into the muscle, and a degree of muscle regeneration in the folds or in the so it would be a combination of factors, how the mesh how the muscle strands become inside the mesh pores or folds.  Q. And you can't say when you look at a specimen, how that muscle and mesh got to where they are?  A. Depends. In some specimens, the mesh just cuts through the muscle, and you see the trail of the muscle, it just sifts through it.  Then I can say for sure the mesh migrated into the muscle, it left behind. But now muscle is interrupt, because mesh just went through it. But sometimes it's an array of different things, so I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	movements, and yeah, you can do it. I mean, you can see well, as long as mesh is mobile. If it's so tight that it's not mobile anymore, like if it's saw it here in between pubic bones, then it will not be mobile. But it doesn't allow that muscle is trying to contract, it just cannot move it anymore because it's so immobile.  Q. And you're talking about various scenarios that you could understand based on your training and experience, correct?  A. That's correct.  Q. You're not talking about findings that you've seen based on an experiment using, for instance, 3D ultrasound technology that you, yourself, have performed, right?  A. No. I'm basing what I see on the microscope. If it's healthy muscle, within the mesh, completely surrounded by the mesh, it's contraction will cause movement of the muscle.  Q. And you haven't tested your hypothesis about how muscle contraction will

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Page 302
                                                                                                      Page 304
 1
      This is my interpretation of the microscopic
                                                            1
                                                                        MR. ORENT: Objection.
 2
      findings, that's what I'm trained to do. Interpret
                                                            2
                                                                        BY MS. BYARD:
                                                            3
 3
      what I see in the microscope, so...
                                                                        Q. -- right?
                                                            4
                                                                        A. That's correct.
 4
              BY MS. BYARD:
 5
              Q. You haven't tested that finding in
                                                            5
                                                                        O. There are ways to measure the
                                                            6
 6
      living patients, right?
                                                                 forces at work in the body, aren't there?
 7
             MR. ORENT: I'm not sure if he was done
                                                            7
                                                                        A. You have to explain a little bit
                                                            8
 8
      with his prior answer.
                                                                 more, what do you mean "forces in ways --"?
                                                           9
 9
              BY MS. BYARD:
                                                                        Q. Well, there are ways that you
10
                                                          10
                                                                could measure, for instance, the intraabdominal
              Q. Oh, sorry.
11
              A. See, this is not my job, I mean, I
                                                          11
                                                                 force placed on muscle through, through ultrasound
12
      know what tissue does. So if a muscle is healthy,
                                                          12
                                                                technology, can't you?
13
      it contracts. This is what we know based on --
                                                          13
                                                                        MR. ORENT: Objection. Vague.
                                                          14
14
                                                                        THE WITNESS: I'm not sure if you can
      mesh, no mesh, we've known it for thousands of
                                                          15
15
      years, muscle contracts. If it's healthy muscle,
                                                                 use ultrasound to measure the force.
16
      it contracts. If it is in the mesh and completely
                                                          16
                                                                        For diagnostic purposes, I don't --
17
      surrounded by the mesh, the contraction will pull.
                                                          17
                                                                 well, I mean, first of all, I'm not sure if it can
      So this is my interpretation as a pathologist.
                                                          18
                                                                be done. Second, I don't see diagnostic purpose,
18
19
              If I measured what the strength, what
                                                          19
                                                                and I certainly wouldn't expect it to be done for
20
      the force it produces in that specific section, no,
                                                          20
                                                                diagnostic purposes.
21
      but I don't have to. Because my job is
                                                          21
                                                                        BY MS. BYARD:
                                                          22
22
      interpretation, and that is my interpretation.
                                                                        Q. Are you familiar with something
23
              Q. Okay. So in answering my
                                                          23
                                                                called "urodynamic testing"?
24
      question, have you tested this yourself in humans,
                                                          24
                                                                        A. Urodynamic is different.
25
      in living humans, your answer would be, "no"?
                                                          25
                                                                        Q. How so?
                                            Page 303
                                                                                                      Page 305
             MR. ORENT: Objection.
 1
                                                            1
                                                                        A. Well, then they measure forces and
 2
             THE WITNESS: No. I mean, I explained
                                                            2
                                                                 pressures to understand what's causing urinary
 3
      to you that I interpret based on what we know about
                                                            3
                                                                symptoms.
 4
      tissue reaction and general physiology of humans.
                                                            4
                                                                        Q. And they measure the forces of
                                                            5
 5
                                                                 various intraabdominal contractions, or the
             BY MS. BYARD:
 6
                                                            6
                                                                 detrusor muscle contraction --
             Q. Okay. You also write that:
 7
                "Mesh in smooth muscle can
                                                            7
                                                                        A. Detrusor muscle, yes.
 8
             interfere with muscle contraction
                                                           8
                                                                        Q. -- within the female body, right?
             and organ function."
                                                           9
 9
                                                                        A. Yes, there is --
                                                          10
10
             A. Yes.
                                                                        Q. That's not an area that you've
11
             Q. Again, you haven't used any
                                                          11
                                                                studied though, correct?
12
      imaging to test in human beings, how mesh present
                                                          12
                                                                        A. No. No, I have not.
13
      with smooth muscle interferes with muscle
                                                          13
                                                                        MR. ORENT: Counsel, we're at 6:25,
14
      contraction or with organ function, have you?
                                                          14
                                                                we're going to wrap up in about five minutes.
15
             A. I'm not radiologist, I don't use
                                                          15
                                                                        MS. BYARD: Okay. I might be at a good
16
      images -- what I see, I see when the mesh is in
                                                          16
                                                                 stopping point then.
17
      the smooth muscle, I know it went all the way to
                                                          17
                                                                        BY MS. BYARD:
18
      urinary bladder, it's somewhere in the detrusor
                                                          18
                                                                        O. There's also a discussion here of
19
      muscle. I mean, if the bundles are consistent with
                                                          19
                                                                 limited elasticity. And, similarly, there are ways
20
      bladder. It correlates almost 100 percent with
                                                          20
                                                                 to study the elasticity of different tissues within
21
      clinical descriptions of urinary symptoms.
                                                          21
                                                                 the body, aren't there?
22
                                                          22
             Q. So in answer to my question, no,
                                                                        A. Yes, including gross examination,
23
      you haven't studied that in humans because you're
                                                          23
                                                                which I do.
24
      not a radiologist and that's not in your area of
                                                          24
                                                                        Q. But there is testing that can be
25
      study --
                                                          25
                                                                done beyond gross examination, right?
```

77 (Pages 302 to 305)

	Page 306		Page 308
1	A. For my purposes, we are not doing	1	Q. Well, in a normal healthy person,
2	more than that as a pathologist. If it's done for	2	you wouldn't see pelvic organ prolapse to begin
3	any other diagnostic procedures, I'm not aware of	3	with, would you? That's an abnormal finding?
4	commonly used diagnostic tool which would use	4	MR. ORENT: Objection.
5	elasticity for a specific diagnosis.	5	THE WITNESS: Partially, it's a
6	Q. Well, researchers have looked at	6	relaxation, age-related; so what do you mean? I
7	the elasticity of virgin tissue compared to scar	7	mean, healthy younger individual, yes, this would
8	tissue, haven't they?	8	be a problem.
9	A. Well, that's research. Research	9	BY MS. BYARD:
10	and clinical practice are different areas, I	10	Q. Similarly, stress urinary
11	•	11	incontinence is an abnormal finding, isn't it?
	mean	12	A. Yes.
12	Q. So irrespective of whether it's in		
13	research or clinical practice, there are ways to	13	MS. BYARD: Okay, Doctor, I think we've
14	look at the relative elasticity of different types	14	reached a good stopping point for the night. I
15	of tissues?	15	thank you for your time.
16	MR. ORENT: Objection.	16	THE WITNESS: Thank you.
17	BY MS. BYARD:	17	THE VIDEOGRAPHER: This marks the end
18	Q. True?	18	of media number four in today's proceedings in the
19	A. Yes. I mean, mostly for research,	19	deposition of Dr. Vladimir Iakovlev.
20	as I expect. Maybe there is a very limited amount	20	We are going off the record at 6:31 p.m.
21	of clinical applications, like for genetic	21	
22	conditions when there is not enough collagen or	22	Whereupon the deposition was suspended at 6:31 p.m.
23	something else, I mean, but	23	
24	Q. Or with pelvic organ prolapse,	24	
25	too, where there are different types of collagen	25	
	Page 307		Page 309
1	present at different levels that lead to	1	REPORTER'S CERTIFICATE
2	abnormalities in the structures of the pelvis?	2	
3	A. I don't think it is not. Pelvic	3	
4	organ prolapse is just by visual assessment and	4	I, JUDITH M. CAPUTO, RPR, CSR, CRR,
5	degree of prolapse.	5	Registered Professional Reporter, certify;
6	Q. Do you know how the presence of	6	That the foregoing proceedings were
7	different types of collagen in the pelvic floor	7	taken before me at the time and place therein set
8	correlate to incidence of pelvic organ prolapse in	8	forth, at which time the witness was put under oath
9	women?	9	by me;
10	MR. ORENT: Objection.	10	That the testimony of the witness and
11	THE WITNESS: Collagen alteration, the	11	all objections made at the time of the examination
12	ratios, I mean, they affect not just pelvic organ	12	were recorded stenographically by me and were
13	prolapse, they affect the whole body. There will	13	thereafter transcribed;
14	be abnormalities, aortic dilatation and	14	That the foregoing is a true and
	· · · · · · · · · · · · · · · · · · ·	15	correct transcript of my shorthand notes so taken.
15	hyperelasticity of joints and so forth. So it's	16	
16	not just pelvic organs which are affected.	17	
	BY MS. BYARD:	18	
17	O Destado de estado de C		D 4 141: 22 1 1 CD 1 2014
18	Q. But that's not an area of your	19	Dated this 23rd day of December, 2014.
18 19	study, right?	20	Dated this 23rd day of December, 2014.
18 19 20	study, right?  A. But this would be an abnormal	20 21	Dated this 23rd day of December, 2014.
18 19 20 21	study, right?  A. But this would be an abnormal genetic condition, if we talk about collagen	20 21 22	Dated this 23rd day of December, 2014.
18 19 20 21 22	study, right?  A. But this would be an abnormal genetic condition, if we talk about collagen alteration.	20 21	· 
18 19 20 21 22 23	study, right?  A. But this would be an abnormal genetic condition, if we talk about collagen alteration.  If it's a normal, healthy person, I	20 21 22 23	PER: JUDITH CAPUTO, RPR, CSR, CRR
18 19 20 21 22	study, right?  A. But this would be an abnormal genetic condition, if we talk about collagen alteration.	20 21 22	· 

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	Page 310		Page 312
1	CERTIFICATE OF REPORTER	1	** ERRATA SHEET **
2	CANADA )	2	
3	PROVINCE OF ONTARIO )	3	NAME OF CASE: IN RE: BOSTON SCIENTIFIC CORP.,
4	THE VENUE OF SINIAMS /	4	PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
5	I, Judith M. Caputo, the officer before whom the	5	MDL NO. 2326
6	foregoing deposition was taken, do hereby certify	6	DATE OF DEPOSITION: DECEMBER 17, 2014
7	that the witness whose testimony appears in the	7	NAME OF WITNESS: VLADIMIR IAKOVLEV, M.D.
8	foregoing deposition was duly sworn by me; that the	8	
9	testimony of said witness was taken by me in	9	PAGE LINE FROM TO
10	shorthand, using Computer Aided Realtime, to the	10	
11	best of my ability and thereafter reduced to	11	
12	written format under my direction; that I am	12	
13	neither counsel for, related to, nor employed by	13	
14	any of the parties to the action in which the	14	
15	deposition was taken, and further that I am not	15	
16	related or any employee of any attorney or counsel	16	
17	employed by the parties thereto, nor financially or	17	
18	otherwise interested in the outcome of the action.	18	
19		19	
20		20	
21		21	
22	Judith M. Caputo, RPR, CSR, CRR	22	
23		23	
24	Commissioner for taking	24	
25	Oaths in the Province of Ontario	25	VLADIMIR IAKOVLEV, M.D.
	Page 311		Page 313
1	INSTRUCTIONS TO WITNESS	1	PROVINCE OF ONTARIO )
2	INSTRUCTIONS TO WITHLESS	2	TORONTO REGION )
3	Read your deposition over carefully.	3	,
4	It is your right to read your deposition and make	4	
5	changes in form or substance. You should assign a	5	
6	reason in the appropriate column on the erratum	6	I, the undersigned, declare under penalty
7	sheet for any change made.	7	of perjury that I have read the foregoing transcript,
8	After making any changes in form or	8	and I have made any corrections, additions or
9	substance, and which have been noted on the	9	deletions that I was desirous of making;
10	following erratum sheet, along with the reason for	10	That the foregoing is a true and
11	any change, sign your name on the erratum sheet and	11	correct transcript of my testimony contained
12	date it.	12	therein.
13	Then sign your deposition at the end of	13	
14	Your testimony in the space provided. You are	14	
15	signing it subject to the changes you have made in	15	VLADIMIR IAKOVLEV, M.D.
16	the erratum sheet, which will be attached to the	16	
17	deposition before filing. You must sign it in	17	
18	front of a witness. The witness need not be a	18	Subscribed and sworn to before me this
19	notary public. Any competent adult may witness	19	Day of, 2014 at
20	your signature.	20	,
21	Return the original erratum sheet	21	(City) (Province)
22	promptly. Court rules require filing within 30	22	
23	days after you receive the deposition.	23	
24		24	(Notary Public)
25		25	My Commission Expires:

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